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ISSN: 2278-4772

*Ayurpharm Int J Ayur Alli Sci., Vol. 3, No. 8 (2014) Pages 222 – 229*

*Research Article*

# A CONTEMPLATIVE STUDY ON THE CLINICAL EVALUATION AND EFFICACY OF SELECTIVE HERBO-MINERAL FORMULATIONS IN VISHAMA JWARA (MALARIA)

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Received: 07-08-2013; Revised: 05-06-2014; Accepted: 10-08-2014

**Abstract**

Three Clinical Studies were conducted on Single / Compound Ayurvedic Herbal and Herbo-mineral formulations in various institutes at OPD level under Central Council for Research in Ayurveda and Siddha. The objective of the study was to find out the therapeutic efficacy of Ayurvedic formulations in the Management of Vishama jwara (Malaria). Malarial cases which are positive for *Plasmodium vivax* parasite on peripheral blood smear with the symptoms and signs on Vishama Jwara were selected for the study. After completion of therapy, the results were assessed on the basis of clinical features and pathological investigations. Different combinations of herbo-mineral preparations were evaluated under three studies viz. (1) Ayush-64 with Sphatika Bhasma and Guduchi Ghana Satwa, (2) Saptaparna twak Ghanavati, (3) Parijata Patra Ghanavati respectively. All the formulations exhibited around 70-80% therapeutic effect as all the three trial drugs had shown efficacy in curing malaria. More number of patients were found smear negative after the completion of the therapy with Ayush-64 Sphatika Bhasma and Guduchi Satwa and Sapta Parna Twak Ghanavati in comparison to Parijata Patra Ghanavati. No side effects were observed during the course of the clinical trials. Thus, these studies reveal that the above said trial drugs can be used as a safe and effective treatment for Malaria.

**Key Words:** Vishamajwara, Malaria, *Plasmodium vivax*, Anti-malarial.

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*Cite This Article*

Prameeladevi K, Srinivas P. A contemplative study on the clinical evaluation and efficacy of selective herbo-mineral formulations in vishama jwara (Malaria). Ayurpharm Int J Ayur Alli Sci. 2014;3(8):222-229.

www.ayurpharm.com
ISSN: 2278-4772
*Ayurpharm Int J Ayur Alli Sci., Vol. 3, No. 8 (2014) Pages 222 – 229*

## INTRODUCTION

Malarial fevers recognized as distinct clinical entities as early as 5th Century B.C. or even earlier in the east as well as west had been described by Susrutha and Charaka. The nomenclature of the disease, the aetiopathology and method of treatment may be different. But, the clinical picture of the disease is more or less the same. Some of the fevers under Vishama Jwara with irregular onset and remissions like Santata Jwara, Satata Jwara, Anyedyushka Jwara, Triteeyaka Jwara and Chathurthaka Jwara etc. described in the Ayurvedic classics.[1] Malarial fevers caused by various species like *Plasmodium vivax*, *Plasmodium falciparum*, *Plasmodium ovale* and *Plasmodium malaria*. *P. vivax* and *P. falciparum* together cause nearly 95% of malaria infected. The western medicine traces the history of malaria to the Greek and Arabic medicines. The credit of recognizing it as a separate clinical entity should go to vedic and Ayurvedic classics, it was known as Takma in Vedic lore. The knowledge of masakas, makshikas etc. in the causation of certain sankriamika rogas has been acknowledged since ancient times.

Malaria is a protozoal disease[2] transmitted by the Anopheles mosquito, caused by minute parasitic protozoa of the genus *Plasmodium*, which infect human and insect hosts alternatively. It probably originated in Africa and is accompanied with human migration to the Mediterranean shores, India and South East Asia.[3] In the past it used to be common in the marshy areas around Rome and the name is derived from the Italian, mal-aria or "bad air"; it was also known as Roman fever. W.H.O in the wake of Global resurgence reaffirms malaria eradication as the ultimate goal of the program & control as an intermediate objective.

### Advantage of alternate medicines

Ayurveda the traditional system of medicine, existing since centuries have recommended numerous combinations of treatment for different varieties of fever including fevers of chronic and irregular nature.

## MATERIALS AND METHODS

Total 3 clinical studies were carried out at OPD level, single blind clinical trial according the criteria of selection, Malaria cases with typical fever and rigor confirmed on microscopical examination of presence of *Plasmodium vivax* parasite on JSB stained peripheral blood thick smear were recruited into the study.

### Study I

Tab. Ayush 64 – 1g, along with Spatika bhasma (Sulphate of Alumina and potash) 500 mg and Guduchi (*Tinospora cordifolia*) satva 500 mg TID for 7 days

### Study II

Saptaparna (*Alstonia scholaris* R. Br.) twak ghanavati – 500mg TID for 7 days

### Study III

Parijatha pathra ghanavati –1.5g dose TID for 7 days

### Laboratory Investigators

Before administration of the drugs, initial blood smear was taken and urine test for Chloroquine was carried out. The drugs were given for 7 days and every alternative day blood smear was taken (0 day, 2 day, 4th day and 7th day, in follow-up visits test was done on15th day and on 29th day to observe the parasite clearance) and urine test for Chloroquine on 0 day only done.

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**Criteria for Inclusion of the patients**

1. Age above 10 years and below 65 years
2. Periodic fever with chill and rigor
3. Positive peripheral blood smears for *P. vivax*

**Criteria for Exclusion of the patients**

1. Age below 10 years and above 65 years
2. Malaria during pregnancy
3. Malignant Malaria
4. Mixed infections of Malaria

**Criteria for withdrawal**

1. Irregular treatment and follow-up
2. Development of any serious complication during the study

Duration of the clinical trial period (follow-up) was 29 days.

**Criteria for assessment of results of treatment**

***Good Response***

Parasite clearance till 29$^{th}$ day and complete relief from presenting clinical symptoms

***Poor Response***

Complete relief from presenting clinical symptoms and Parasite clearance on day 8, but reappearance later

***No Response***

No parasite clearance on day 8 and no relief from presenting clinical symptoms

**Parameters for assessment of Results**

***Subjective parameters***

Fever, Chills, Rigors, Sweating, Nausea, Vomiting, Giddiness, Body ache.

***Objective parameters***

Peripheral blood smear

**Statistical analysis**

The data on score of subjective parameters like fever, chills, rigor, sweating etc and objective parameters i.e. blood smear was analysed using non-parametric Wilcoxon 't' test.

## RESULTS

**Study I**

Tab. Ayush 64 - 1g, along with Spatika bhasma 500 mg and Guduchi satva 500 mg TID for 7 days

Totally 1194 patients were studied with AYUSH 64, Sphatika bhasma (Sulphate of Alumina and potash) and Guduchi (*Tinospora cordifolia*) satva. Among the 1194, 722 (60.97%) were males, 466 (39.03%) were females. In this study before treatment, 404, 393, 375, 382, 229, 292, 206, 256,251, 238 cases were having fever, rigor, chill, sweating, nausea, vomiting, giddiness, bodyache, headache respectively. After the completion of the treatment 113, 31, 54, 21, 37, 31, 38, 102, 75 cases were only having above said symptoms in the same order. The difference was found ($P<0.001$) statistically significant. Out of 1194, 429 (47.88%) cases had shown Good response, 310 (34.60%) cases had shown Fair response, 127 (14.17%) cases had shown Poor response, 30 number of patients did not shown any response and 298 patients were dropped out from the study due to irregular drug intake and follow ups.

In Good response cases, majority i.e. 71 out of 199 were seen under 20 – 30 years age group and majority of them were males (120). 123 out of 199 Good response cases were with more than 6 days duration of illness. Majority of the Good response cases were found with

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Ayurpharm Int J Ayur Alli Sci., Vol. 3, No. 8 (2014) Pages 222 – 229

Vatapittaja (81), Sariraka prakriti and Rajotamas (87). On the assessment of objective parameters i.e. Peripheral blood smear was found positive for *P. vivax*, in all the 896 cases before the treatment and the smear became negative in 429 cases after the completion of therapy.

AYUSH 64 is a coded drug containing four ingredients Saptaparna (*Alstonia scholaris* R. Br.) Kiratatikta (*Swertia chirayita* (Roxb.ex Flem) Karsten), Latakaranja (*Caesalpinia bonduc* (Linn.) Roxb.) and Katuka (*Picorrhiza kurroa*). To enhance the therapeutic efficacy of the trial drug, Sphatika bhasma (Sulphate of Alumina and potash) and Guduchi satwa were added along with AYUSH 64.

**Study II**

Study II was carried out with Saptaparna (*Alstonia scholaris* R. Br.), twak (bark of *Cinnamomum zeylanica*) ghanavati in 573 cases, of which 200 patients were under 10-20 age group and 179 were under 20-30 age group and 384 were males and 189 were females. Before treatment, 403, 354, 347, 354, 204, 244, 166, 234, 314, 272 cases were having fever, rigor, chills, sweating, nausea, vomiting, giddiness, body ache and headache respectively. After the completion of the treatment 82, 33, 48, 51, 54, 22, 36, 87, 86 cases were having above said symptoms in the same order. The difference was found ($P<0.001$) statistically significant. Out of 573, 194 (48.15%) cases had shown Good response, 127 (31.51%) had shown Fair response, 43 (10.66%) had shown Poor response, 39 (09.68%) did not shown any response and 170 patients were dropped out from the study due to irregular drug intake and follow ups.

In Good response group out of 194, majority i.e. 62 cases under 10-20 years age group 51 cases under 20 – 30 yrs age group was seen and majority of them were males (120). Out of 194 Good response cases, 109 cases were with more than 6 days duration of illness. Majority of the Good response cases were found with Vatapittaja (177), Pittakaphaja (178), Sariraka prakriti and Rajotamas (164). On the assessment of objective parameters i.e. Peripheral blood smear, was found positive for *P. vivax* malaria in 403 cases before the treatment and the smear became negative in 194 cases after the completion of therapy.

**Study III**

Study III was carried out with Parijata patra Ghanavati in 430 cases; of which 162 cases were under 10-20 years age group and 137 cases were under 20-30 years age group and 326 were males and 104 were females. In this study, before treatment out of 310, 262, 222, 232, 150, 125, 116, 163, 205, 118 were having fever, rigor, chills, sweating, nausea, vomiting, giddiness, bodyache, headache respectively. After the completion of the treatment this number reduced to 37, 21, 33, 10, 25, 03, 15, 32, 33 respectively. The difference was found ($P<0.001$) statistically significant. Out of 310, 157 (50.64%) cases had shown Good response, 62 (20.00%) cases had shown Fair response, 54 (17.42%) cases had shown Poor response, 37 (11.94%) cases did not show any response and 120 cases were dropped out from the study due to irregular drug intake and follow ups.

In Good response group out of 157; majority i.e. 44 cases seen under 10-20 years age group 59 cases were seen under 20 – 30 years age group and majority of them were males (103). Majority of the Good response cases were with 03 days duration of illness. Most of the Good response cases were found with Vatapittaja (166), Pittakaphaja (76), Sariraka prakriti and Satvarajas (110), Rajotamas (90). On the assessment of objective parameters i.e. peripheral blood smear was positive for *P. vivax* malaria in 310 cases before the treatment and the smear became negative in 157 cases after the completion of therapy.

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ISSN: 2278-4772
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## DISCUSSION

Chemotherapy is the well-established therapy for malaria, but drug resistance in *Plasmodium* parasite is the major disadvantage. In Ayurveda, Jwara (fever) is considered as an important disease and a comprehensive treatment regimen are described to cure it in radical manner, including recurrent and chronic fevers. The probable mode of action of the trail drugs are summarised here under.

### Mode of action of drugs

All the four components of AYUSH 64 (viz. *Saptaparna* (*Alstonia scholaris*), *Latakaranaja* (*Ceasalpina bundac*), Katuki (*Picorrhiza kurroa*), Kiratatikta (*Swertia chirata*)[4],[5],[6],[7][8][9][10][11] in study I are having tikta, kashaya rasa, laghu, ruksha guna. These properties of the above drug can pacify the pradhana dosha of jvara i.e. pitta and the tikta, kashya rasa of these drugs are raktasodhaka (blood purifier) in nature. This property might have helped in clearing the parasites from the blood. Three out of four drugs of AYUSH 64 are having ushna virya, thereby they can pacify vata which is responsible for chills, rigors, nausea, vomiting, giddiness, body ache and headache.

Sphatika bhasma is proved to be useful in preventing rigors in chronic malarial cases. Hence in this study also it might have helped in prevention of rigors.[12]

Guduchi is having tikta, kashaya rasa and madhura vipaka and tridosha samaka properties. The jvarahara property of Guduchi might have worked in synergy with the above two drugs in combating Malarial symptoms.[13][14]

In study II, Saptaparna ghanavati, Saptaparna (*Alstonia scholaris* R. Br.)[4] is the only ingredient and it is having tikta, kashaya rasa, laghu, snigdha guna, ushna veerya, and katu vipaka. It is having actions like kushthaghna, vranashodhana-ropana, deepana, anulomana, yakridbalya, krimighna, raktashodhaka, hridya, stanyajanana, vishama jwaraghna etc. It is indicated in Jvara, vishama jvara, atisara, pravahika, charma roga, krimi. The drug is found to have hypotensive, anticancer, antimicrobial, anti-malarial, CNS depressant (picrinine); monoamine oxidase inhibitory as well as anti-depressant activities. In study III, Parijatha (*Nyctanthes arbortristis* Linn.) is having tikta rasas, katu vipaka and usna veerya and having Vatakapha samaka, pitta saaraka, vedanasthapana, krimighna, yakritotthejaka, vishgna, raktasodhaka properties. The drug found to have anti-malarial, anti-pyretic, anti-microbial properties on pharmacological screening. 50% Ethanolic extract of aerial part exhibited insecticidal effect. [15][16]

### Effect of therapy

In study I, Ayush-64 along with Sphatika bhasma and Guduchi satva was given for 1194 of patients. Out of 896 completed cases 429 (47.88%) cases got complete relief from malarial sytmptoms and clearance of parasitemia from blood. (Figure 1)

In study II, Saptaparna tvak ghanavati Out of 403 completed cases, 194 (48.15%) had got relief from symptoms of malaria and clearance of parasitemia in the blood. And 127 (31.51%) got complete relief from malaria symptoms. and heavy parasite load also reduced from blood. (Figure 2)

In study III, Parijata patra ghanavati was given to 430 cases, of which 310 cases had completed the treatment. Out of 310, 157 (50.64%) had got relief from symptoms of malaria and clearance of parasite from the blood. And 62 (20.00%) got relief from all the symptoms of malaria and heavy load of parasites reduced from the blood. (Figure 3) On overall review, high percentage of results as noted under study I (82.48%) and in study - II (79.66%).

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Ayurpharm Int J Ayur Alli Sci., Vol. 3, No. 8 (2014) Pages 222 – 229

**Figure 1: Effect of the trial drug on symptoms (Study 1)**

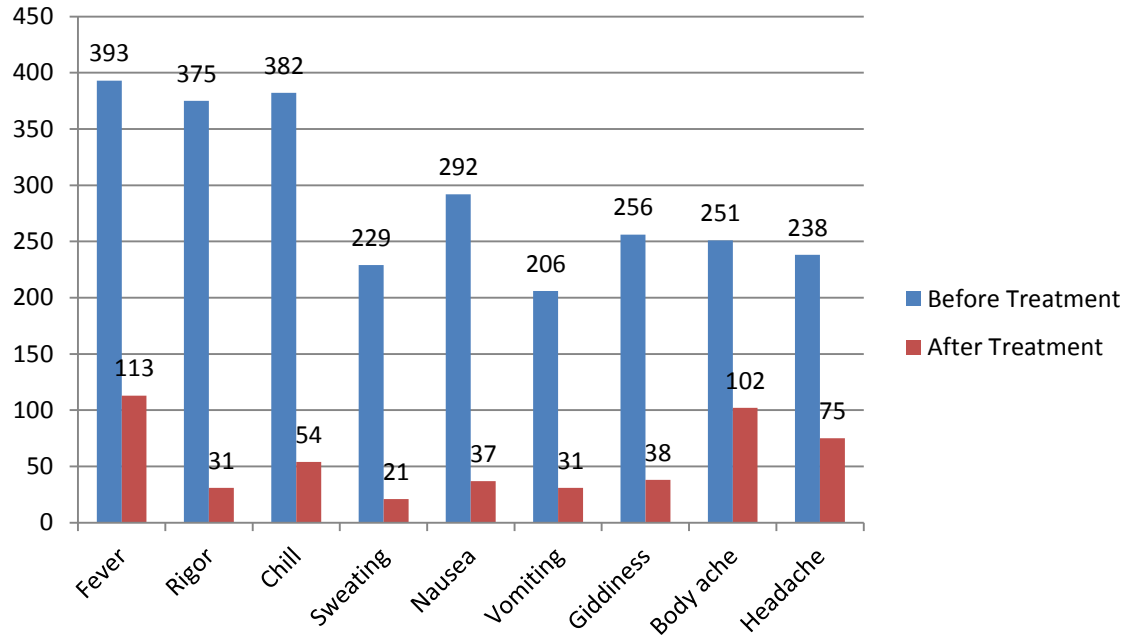


**Figure 2: Effect of the trial drug on symptoms (Study 2)**

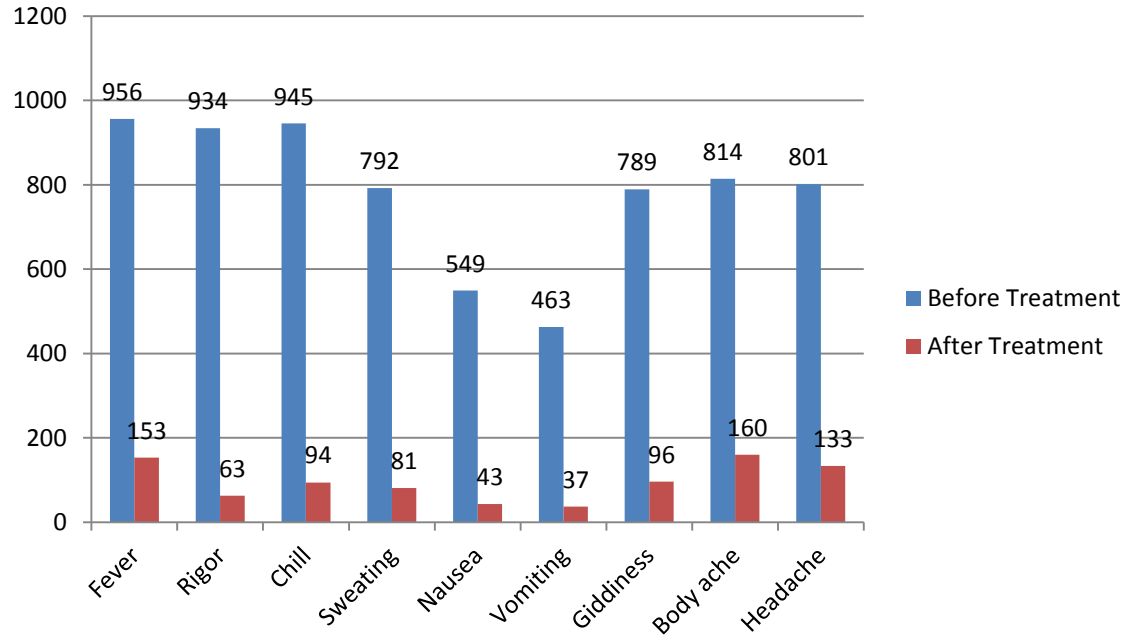

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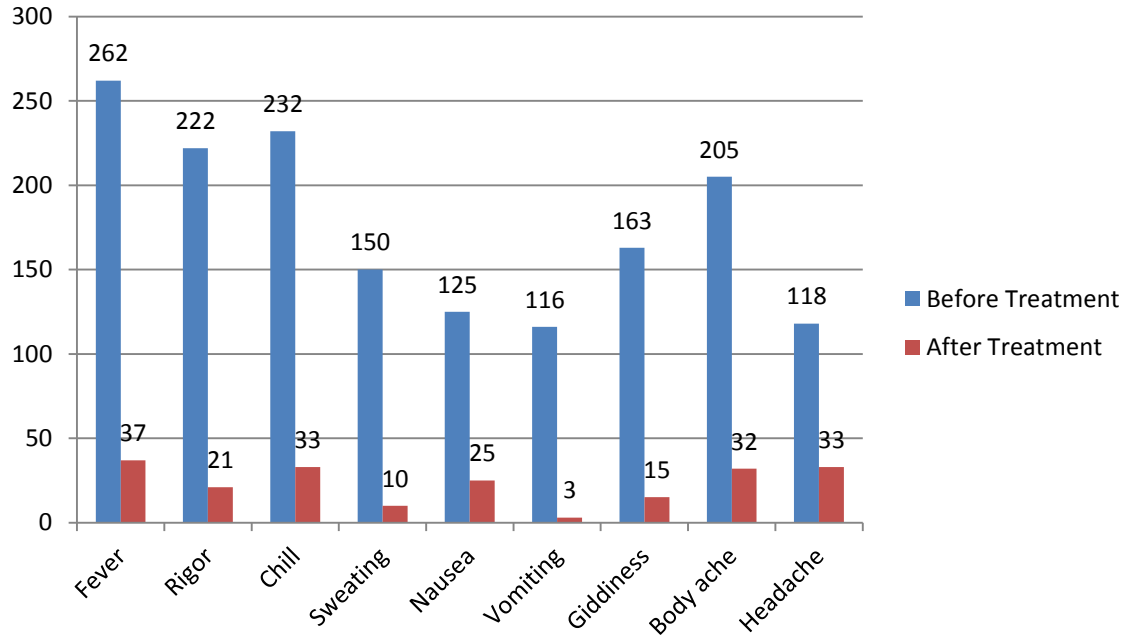
**Figure 3: Effect of the trial drug on symptoms (Study 3)**




## CONCLUSION

All the formulations exhibited around 70-80% therapeutic effect as all the three trial drugs had shown efficacy in curing malaria. More number of patients were found smear negative after the completion of the therapy with Ayush 64 Sphatika Bhasma and Guduchi Satwa and Sapta Parna Twak Ghanavati in comparison to Parijata Patra Ghanavati. No side effects were observed during the course of the clinical trials. Thus, these studies reveal that the above said trial drugs can be used as a safe and effective treatment for Malaria.

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Source of Support: Nil
Conflict of Interest: None Declared