

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF A HERBAL FORMULATION (VATA-RAKTA HARA YOGA) IN THE MANAGEMENT OF VATA-RAKTA W.S.R. TO GOUT

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ABSTRACT

With the increasing availability of resources, the human race is adopting the life style which is predominantly sedentary in nature. Along with this, food rich in calories and proteins, and use of alcoholic beverages is increasing. These 2 factors are responsible for many diseases, and *Vata Rakta* is one of them. *Vata-Rakta* is an agonising joint disease, which has humiliated mankind since long. Severe pain, swelling, tenderness, burning sensation and restricted joint movements due to pain, compromise the efficiency of the sufferer. Despite the elaborate knowledge of pathogenesis of the disease and availability of various drugs with Modern and *Ayurvedic* systems of medicine, proper management has yet not become possible. To provide relief to the ailing humanity with help of safer *Ayurvedic* drugs, this study was conceptualised. The drug used in the study was *Vata Rakta har Yoga*, which is combination of three herbs, *giloye* (*Tinospora cordifolia*), *manjishtha* (*Rubia cordifolia*) and *suranjana*. Before administration of the trial drug, *Haritaki churna* was given to the patients for *koshtha shudhhi*. The results were analysed using appropriate statistical tests. All these herbs possess various pharmacological activities like anti inflammatory, analgesic and uric acid lowering. These properties help reduce the symptoms of *Vata Rakta*. Positive effect was also observed on the serum uric acid. It was concluded that *Vata rakta Har yoga* is effective in alleviating the Signs and Symptoms as well as in bringing down the raised Serum Uric acid levels.

Keywords: *Vatarakta*, Gout, *Ayurveda*

INTRODUCTION

Diseases have afflicted humanity since the very beginning and have inspired the human being to face them and fight boldly against them and he has played his role very efficiently. This is very much evident from his survival through long journey of life.

Ayurveda is one of the oldest systems of medicines. History of the Indian system of medicine reveals that the Brahma was the first to propound this art. *Ayurveda* composed by him deals extensively with all aspects of life including the illnesses. It has been divided in eight separate specialities, and was called *Ash-tanga Ayurveda*, which indicates how advanced this system was at that time also. The main aim of *Ayurveda* is to provide a quality life to the humans. That is why the emphasis has been laid on the preventive aspect of the disease¹. This is evident from the fact that before planning the management of diseases, description of *Dincharya* and *Ritucharya* is given.

Ayurveda is working since long in the direction of WHO's motto of "Health for all." Despite marked advancements in field of modern medicine, mankind is still suffering from many different diseases. *Vata-Rakta* is one of them; and is a disease which is very distressing due to its chronic relapsing and remittent nature. Description of *Vata-Rakta* on the basis of aetiological factors, clinical features and prognosis is similar to Gout as described in modern medicine. Recurrent attacks of agonising pain, inflammation and restricted movements make the sufferer's life miserable. Multifactorial efforts have been made to get rid of the problem, but still it remains a challenge for modern medicine to find some safe and sure

cure for this disease. Even course of the disease has not changed much with available remedies. Major contributory factors like protein rich diet, consumption of alcohol and sedentary life style have become a part of normal routine.

Vata-Rakta is a problem of high socio-economic society. *Charaka* has also called it as *Adhya-Vata*² i.e. disease affects mostly the people from higher economic groups.

Classical *Ayurvedic* texts are loaded with plenty of references and detailed description of the disease under the name of *Vata-Rakta*, *Vata-Balasa*, *Adhya-Vata* and *Khudda-Vata*. Long list of drugs have been recommended for the management and some of them are practically being used, but permanent cure has not been sorted out so far.

Considering the agony associated with the disease, the losses met by the sufferer and the aim to provide relief to the ailing society from this disease so that the people continue to be productive for society, the disorder has been considered for the study keeping in mind the dire need of the hour to find some safe, sure and permanent cure effective for the disease.

Hence the present study was planned for clinical research work to study the disease and its management. In this study the formulation used was a combination of three drugs i.e. *Guduchi*, *Manjishtha* and *Suranjana* for the management of *Vata-Rakta*. In this study 20 patients were enrolled. They were prescribed *Haritaki churna* 3-6 gms depending upon the bowel habits of the patient at bed time for 3 to 5 days, then they were given the trial drug *Vata-Rakta hara yoga* in a dose depending upon the weight of the patients. Patients

weighing upto 45 kg were given 3 gm/day of the trial drug in divided doses, patients weighing 45 to 60 kg were given 4 gm/day and patients above 60 kg were given 5 gm/day of the drug in divided doses. The therapy was given for 45 days. Relief in clinical symptoms and reduction in serum Uric acid was considered as main criteria for assessing the effect of the therapy.

MATERIALS AND METHODS

Selection of the Patients

The patients were selected from OPD/IPD of P. G. Department of Kayachikitsa, R.G.G.P.G. Ayurvedic College and Hospital, Paprola. The patients were selected irrespective of sex, caste and religion. The patients who presented with signs and symptoms of *Vata-Rakta* were selected for the study.

Diagnostic Criteria

The patients were diagnosed on the basis of *Ayurvedic* and Modern parameters. Among clinical signs and symptoms, following parameters from classical texts were considered for the diagnosis.

1. *Sandhi Shoola*
2. *Sandhi Shotha*
3. *Raga*
4. *Vidaha*
5. *Sparsh Asahyata*
6. *Twak Vaivarnya*
7. *Visphota*
8. *Sandhi Vikriti*

Serum Uric acid was considered as investigation based diagnostic tool.

Criteria of Inclusion of Patients

The patients fulfilling the following criteria were included in the study.

Subjective Criteria

In these criteria, signs and symptoms of *Vata-Rakta* as mentioned above were considered. Only those patients were included who had the signs and symptoms of *Vata-Rakta*.

Investigation Based Criteria

The Patients with raised Serum Uric acid level were included.

Criteria of Exclusion

The patients not willing to participate in the trial were excluded from the study. In addition patients suffering from other serious medical illnesses like PTB, carcinomas, CHF etc. were excluded from the study. Also the patients with serious complications of Gout and those who were about to undergo surgery were excluded.

Protocol of Research

Institutional Ethics committee approval was taken before conducting the clinical trial.

Consent of the Patients

An informed and written consent was obtained from all the patients who were diagnosed as suffering from *Vata-Rakta* and were willing to participate in the trial. The whole procedure, nature of study, drugs, aims and objectives, possible benefits and hazards were explained to the patients. The patient's queries, if any, were satisfactorily answered. The willing patients were required to sign the consent.

Clinical Research Form

A special proforma was prepared to record the history of the patients in detail. This proforma included patient registration no., presenting

complaints, history of present and past illnesses, drug history, family history, personal history, socioeconomic history, general physical examination, *Ashtavidha pariksha*, *Dashavidha pariksha*, systemic examination, provisional diagnosis, laboratory investigations, diagnosis, treatment given and effects of therapy. The proforma was filled before the commencement of study and was maintained throughout the study.

Trial Drug

The formulation used in the trial was a combination of three drugs i.e. *Guduchi*, *Manjishtha* and *Suranjana*. Before administration of the trial drug, the patients were given *Haritaki Churna* for *Kostha shudhi*. The detail of all the drugs used in the trial is as follows.

For *Koshtha Shudhi*:

1. *Haritaki phal Churna* (Powder of fruit of *Terminalia chebula*)

Trial Drug:

1. *Guduchi Churna* (Powder of Stem of *Tinospora cordifolia*) – 1 part
2. *Manjishtha Mool Churna* (Powder of roots of *Rubia cordifolia*) – 1 part
3. *Suranjana Churna* (Powder of corm of *Colchicum luteum*) – 1 part

Preparation of Drugs/Compound

First of all the drugs were procured and got identified in the department of *Dravya Guna* and then were cleaned, dried in shade and fine powder of all the drugs was prepared separately. Powder of *Haritaki* fruits was packed in separate air tight containers. Powder of other three drugs i.e. *Guduchi*, *Manjishtha* and *Suranjana* was taken in equal quantity

according to weight and mixed thoroughly. The half of prepared mixture was packed in air tight containers and remaining half material was filled in gelatin capsules of 500mg each. The capsules were packed in air tight containers.

Mode of Administration and Dose of the Drug

a. *Koshtha Shudhi*

For *Koshtha shudhi*, *Haritaki churna* was given for first 3 to 5 days at bed time in a dose of 3 to 6 gms. depending upon the bowel habits of the patients. The vehicle advised for taking *Haritaki Churna* was lukewarm water.

b. Trial Drug

After *Kostha Shudhi*, the patients were given *Vata-Rakta Hara yoga*. The compound was given in powder/capsule form in requisite dose in divided doses. The dosage of the trial drug was prescribed according to the weight of the patients as follows.

1. Upto 45kg: 3gm per day in divided doses (i.e. 1gm thrice a day)
2. 45kg to 60kg: 4gm per day in divided doses (i.e. 2gm twice a day)
3. Above 60 kg: 5gm per day in divided doses. (i.e. 2.5gm twice a day)

The vehicle advised for the trial drug was water.

Duration of treatment

After *Koshtha Shudhi* all the patients were given trial drug for 45 days and the follow was done every 15 days.

Criteria of Assessment

Subjective Criteria

These criteria included the assessment of presence or absence of signs and symptoms after the treatment. For this purpose a score system was adopted.

Score System

To assess the improvement or effect on subjective parameters, a grade/score system was designed as described below.

A scale was designed with numerical values to be used by patients to describe the status of the symptom.

Similar scale was designed and used for assessment of other features as under:

1. Sandhi Shoola

Score	Pain Status
0	No Pain
1	Mild Pain
2	Pain on movement & relieved on rest
3	Constant Pain
4	Severe Pain disturbing sleep

2. Sandhi Shotha

Score	Swelling Status
0	No Swelling
1	Mild Swelling
2	Moderate Swelling
3	Severe Swelling without loss of movements
4	Severe Swelling with loss of movements

3. Sparsh Asahyata

Score	Tenderness Status
0	No Tenderness
1	Patient says it is Tender
2	Patient says it is Tender and winces

3.	Patient says it is Tender, winces and withdraws the limb.
4.	Patient does not allow touching the affected part

4. Raga

Score	Redness Status
0	No Redness
1	Mild Redness
2	Moderate Redness
3	Severe Redness
4	Joint Dusky Red

5. Twak Vaivarnya

Score	Discoloration Status
0	No Discoloration
1	Mild Discoloration of the skin
2	Moderate Discoloration of the skin
3	Severe Discoloration of the skin

6. Vidaha

Score	Burning Sensation Status
0	No Burning sensation
1.	Mild Burning sensation
2.	Moderate Burning sensation
3.	Severe Burning sensation

7. Visphota

Score	Desquamation Status
0	No Desquamation
1.	Mild Desquamation
2.	Moderate Desquamation
3.	Severe Desquamation

8. Sandhi Vikriti

Score	Deformity Status
0	No Deformity
1.	Mild Deformity of single joint
2.	Deformity of 2-3 joints
3.	Asymmetric Deformity of joint

4. Formation of tophi in multiple joints.

Objective Criteria:-

To assess the effect of therapy on objective parameters, Serum Uric acid level was assessed before and after the treatment.

Statistical Analysis

The information gathered regarding demographic data is shown in terms of percentage. The scores of criteria of assessment were analyzed statistically in terms of mean score B.T. (Before treatment), A.T. (After treatment), (B.T. – A.T.) difference of mean, S.D. (Standard deviation), S.E. (Standard error). Student's paired 't' test was carried out at $p < 0.05$ and $p < 0.001$.

The results were considered significant or insignificant depending upon the value of p.

- Highly significant - $p < 0.001$
- Significant - $p < 0.05$
- Insignificant - $p > 0.05$

Overall Assessment

After completion of the trial, therapeutic effects of treatment were studied as per subjective and objective criteria and were recorded as follows.

Cured:-

- a. Total remission of Signs and Symptoms noted before treatment.
- b. Normalization of Serum Uric acid values after the treatment.
- c. Patients resuming normal routine work without any problem.

Markedly Improved:-

- a. More than 70% relief in Signs and Symptoms

- b. Reduction in Serum Uric acid values to normal or near normal.

Improved:-

- a. 50-70% relief in clinical Signs and Symptoms.
- b. Slight decrease or tendency towards disease in Serum Uric acid.

Unimproved:-

- a. No improvement in Signs and Symptoms
- b. No reduction in Serum Uric acid level.

Deteriorated:-

- a. Aggravation of Signs and Symptoms
- b. Increase in Serum Uric acid.

OBSERVATIONS

In the present study, total 20 patients were registered out of which 4 patients did not complete the study. Therefore the observations are recorded from all 20 patients and the results have been recorded from the 16 patients who completed the study.

It was observed during the trial that maximum number of patients i.e. 40% (8) were between 60-70 years of the age, 65% (13) patients were males, All (20) were of Hindu religion, 35% (7) of the patients were House wives, 35% (7) of the patients were graduate, 82.61% (19) were married, 60% (12) were upper middle class, 35% (7) patients had no addiction and similar number of the patients were addict to alcohol and smoking, 35% (7) of the patients were of *vata-pittaj* and *pitta-kaphaj prakriti*, 90% (18) were from rural area, 60% (12) of the patients were having mixed dietary habits, 50% (10) of the patients were having sedentary life style, 75% (15) were having asymmetrical involvement of joints, 80% (16) of the patients were of average weight, 45% (9)

of the patients had chronicity of the disease for 1-3 years.

Among all the registered patients, 100 % were having the symptoms *Sandhi Shoola*, *Sandhi Shotha* and *Sparsh Asahyata*. 85% (17) of the patients were having *vidaaha*, 80% (16) of the patients were having *raaga*, 60% (12) of the patients were having *vaivarnya*, 10% (2) of the patients were having *visphota* and *sandhi vikriti*.

RESULTS

Table 1: Showing results of Trial Drug on various Symptoms

Sr. No.	Symptoms	'n'	Mean Score		%age relief	SD±	SE	t	p
			BT	AT					
1.	<i>Sandhi Shoola</i>	16	3.19	0.37	88.4	.40	.1	28.1	<.0001
2.	<i>Sandhi Shotha</i>	16	2.25	0.19	91.5	.68	.17	12.1	<.0001
3.	<i>Sparsh Asahyata</i>	16	2.18	0.13	94.26	.68	.17	12.1	<.0001
4.	<i>Raga</i>	14	2.28	0.07	96.9	.36	.09	22.06	<.0001
5.	<i>Vidaha</i>	15	1.93	0.07	96.5	.44	.15	16.9	<.0001
6.	<i>Vaivarnya</i>	10	1.5	0.2	86.6	.48	.15	8.6	<.0001
7.	<i>Visphota</i>	02	1.5	0	100	.70	.5	3	>.05
8.	<i>Sandhi Vikriti</i>	02	1.5	1.5	0	0	0	0	>.05

After completion of the study, 88.4% improvement was seen in *Sandhi Shoola* which was statistically significant with $p < 0.001$. There was 91.5% improvement in *Sandhi Shotha* with statistically significant value of $p < 0.001$. 96.9%, 96.5% and 94.26% improvement was seen in *Raga*, *Vidaha* and *Sparsh Asahyata* respectively which was

Present study showed that out of 20 patients, MTP joint was involved in 85% (17) patients, Ankle joint was involved in 55% (11) patients. 30% (6) patients presented with involvement of Instep of foot. Next in order of frequency were Knee and MCP joints, which were involved in 25% (5) patients each. IP joint was involved in 15% (3) patients whereas Wrist joint was involved in 10% (2) patients.

highly significant statistically with $p < 0.001$. After treatment, *vaivarnya* improved by 86.6% and the improvement was statistically significant with $p < 0.001$. Though 100% improvement was seen in *visphota*, it was not statistically significant with $p > 0.05$. There was no improvement in *Sandhi Vikriti*.

Table 2: Showing Effect of Trial Drug on Serum Uric Acid Levels

Mean BT	Uric Acid AT	% age Relief	SD±	SE±	t	p
8.29	7.03	15.22	.89	.23	5.61	<.0001

The mean Uric acid before treatment in the present study was 8.29 mg/dl. This reduced to 7.03 mg/dl after treatment. This reduction in level of Serum Uric Acid was 15.22%, and was highly significant statistically ($p < .0001$).

OVERALL EFFECTS OF THE THERAPY

Out of 16 patients who completed the study, 6 patients (37.5%) got complete relief in clinical signs and symptoms as well as significant decrease in serum Uric acid level. 4 patients (25%) were markedly improved, i.e. they got more than 70% relief in signs and symptoms; and reduction in serum Uric acid to normal or near normal values. 6 patients (37.5%) were improved, i.e. they got 50-70% relief in clinical features and slight decrease in serum Uric acid. None of patients remained unimproved after the completion of trial and none of the patients deteriorated. Signs and symptoms were not aggravated and no increase in serum Uric acid was noted in any of the patients.

DISCUSSION

In the present clinical study the observation of presence of various cardinal features in patients are as under. All the 20 patients (100%) presented with complaints of *Sandhi Shoola*, *Sandhi Shotha* and *Sparsh Asahyata*. The mean scores of these symptoms were; 3.19 for *Sandhi Shoola*, 2.25 for *Sandhi Shotha* and 2.18 for *Sparsh Asahyata*. In the present study

Raga was present in 80% of the patients with a mean score of 2.28. 85% patients presented with *Vidaha*, with mean score of 1.93. The present study recorded the symptom *Vaivarnya* in 60% of the patients with a mean score of 1.5. In this clinical study, *Visphota* and *Sandhi Vikriti* were observed in 10% patients each, with a mean score of 1.5 each.

Discussion on Effects of Therapy Effect on Clinical Symptoms

After completion of therapy, the relief in *Sandhi Shoola* was 88.4% which was highly significant statistically with value of $p < 0.0001$. 91.5% relief was observed in *Sandhi Shotha*, which was highly significant on statistical parameters ($p < .0001$). The relief was progressive. The present study revealed that there was 94.26% relief in *Sparsh Asahyata* after completion of therapy, which was highly significant statistically with $p < .0001$. Like *Sandhi Shoola* and *Sandhi Shotha*, relief in this symptom was also progressive. In the present study 96.9% relief was recorded in *Raga*. Statistical analysis revealed that improvement was highly significant with $p < .0001$. Relief in this symptom was also progressive. 96.5% relief was recorded in the *Vidaha* after 45 days of therapy. Analysis revealed that the improvement was highly significant statistically ($p < .0001$). In the present study, 100% relief was recorded in *Visphota* after completion of therapy. The improvement was not significant statistically ($p > 0.05$). In the present study relief recorded

in *Vaivarnya* was 86.6%. Statistically this improvement was highly significant with $p < .0001$. In the present study no relief (0%) was observed in the *Sandhi Vikriti*. For the diagnosis and assessment of results, the main laboratory criteria was Serum Uric acid estimation. The mean Uric acid before treatment in the present study was 8.29 mg/dl. This reduced to 7.03 mg/dl after treatment. This reduction was 15.22%. The reduction was highly significant statistically ($p < .0001$)

Sides Effects of Therapy

In the present clinical study, none of the registered patients reported any ill effect of the drug during the therapy. Haematological and biochemical investigations carried out before and after the treatment showed no major change. The above findings suggest that there is no systemic ill effect of the formulation. But the formulation needs to be further evaluated for ill effects on large samples so that the drug can be prescribed for longer duration with complete safety.

Probable Mode of Action

The present clinical study reveals that the formulation used is effective in the treatment of *Vata-Rakta*. The results were appreciable in both the clinical and laboratory criteria. Statistically, relief in *sandhi shoola*, *sandhi shotha*, *raga*, *sparsh asahyata*, *vidaha*, *vaivarnya* and in reduction in serum Uric acid levels was highly significant. The trial drug *Vata-Raktahara yoga* is a combination of three drugs, *Guduchi*, *Manjishtha* and *Suranjana*. *Guduchi* and *Manjishtha* have been used in management of *Vata-Rakta* in *Ayurvedic* lit-

erature. *Suranjana* does not find any reference in the *Ayurvedic* texts but has been used in management of Gout and rheumatism since long by *Unani Vaidyas*.

Apart from this, the basis of selection of above drugs was their properties of alleviating pain, relieving swelling and blood purifying properties. Experimental studies have shown them to be anti-inflammatory, analgesic and having antiarthritic properties. All the drugs in formulation pacify different *doshas* and establish homeostasis of *doshas*. Once the *doshik* homeostasis has been achieved, the signs and symptoms of *Vata-Rakta* are relieved automatically because the disease and its different manifestations are all produced by *doshas*.

Giloye is a *Rasayana* and it pacifies *tridosha*³. Due to its *Tikta Kashaya rasa*, it normalizes *Kapha* and *Pitta*, because of *Guru*, *Snigdha* and *Ushna guna*, it normalizes *Vata dosha*. Other properties of *Guduchi* are *Vednasthapaka*, *Deepana*, *Pachana*, *Pittashamaka*, *Anulomaka*, *Rakta shodhaka*, *Raktavardhaka* and *Daha prashamaka*⁴. It has *deepana* properties as well⁵.

Homeostasis of *doshas* and *deepana* causes clearance of *srotodushti* which is *sanga*⁶ in case of *Vata-Rakta*. Once the *srotodushti* is cleared, the vicious cycle of provocation of *Vata* and *Rakta* is interrupted and relief in symptoms becomes evident. Being *Deepana*, it is *ama pachana*. Retained metabolic wastes can be compared to *ama*, therefore *Guduchi* is supposed to bring down the Serum Uric acid level. It possesses anti-inflammatory⁷ and immunomodulator⁸ properties.

Manjishtha is *Pittashamaka* due to its *Tikta*, *Kashaya* and *Madhura Rasa*. Thus it also

helps cure *Rakta dushti*. *Guru Guna* and *Ushna Virya* pacify *Vata Dosha*⁹, hence it is useful to relieve *Vata vriddhi* also. Moreover, the drug has been said to be *Rakta prasada*¹⁰ (Blood purifier). *Manjishtha* acts as anti-inflammatory^{11, 12}, analgesic¹³ and antipyretic¹⁴.

There is no mention of *Suranjana* in classic texts. *Suranjana* contains colchicine, which is thought to inhibit chemotaxis and the function of polymorphonuclear cells responsible for acute inflammation¹⁵. It is *Shothahara* and *Vednasthapaka*. The drug has reduced Serum Uric acid level in experimental studies on rabbits¹⁶. From the above description it appears that these drugs exert a synergistic effect in breaking the pathogenesis of *Vata-Rakta*. They act as *Rasayana*, improve *Dhatu* formation, are *Tridoshaghna*, *Vatashamaka*, *Raktashodhaka*, *Vedanahara* and therefore relieve signs and symptoms of *Vata-Rakta*.

The drugs are Immunomodulator, help in lowering the Serum Uric acid level, reduce Pain and Inflammation. The formulation has proved effective in relieving cardinal features of *Vata-Rakta*. As the ingredients of this formulation have established properties, it may be inferred that the formulation is safe and suitable in management of *Vata-Rakta*.

CONCLUSION

The present clinical study reveals that *Vata-Rakta* mostly affects the people in 4th to 5th decade of life. Male patients are more prone to disease and prevalence is high in people from high socio-economic group. High protein diet and non vegetarian diet is a definitive aetiological factor. Common presenting features are

Sandhi Shoola, *Sandhi Shotha*, *Sparsh Asahyata*, *Raga*, *Vidaha* and *Vaivarnya*. The drug used in study proved effective in alleviating the signs and symptoms as well as in bringing down the raised Serum Uric acid levels. Statistically, the drug proved ineffective in *Visphota* and *Sandhi Vikriti*. It can be concluded that the formulation *Vata-Raktahara yoga* is quite effective in management of *Vata-Rakta*, thus can be prescribed to patients of the disease for longer duration to prevent the recurrence of attacks without any adverse effects.

As the drug is easily procurable, cost effective and efficient in relieving the signs and symptoms and is free from side effects, it can be quite beneficial to the sufferers in preventing the complications of Hyperuricemia and Gout.

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