

CLINICAL EVALUATION OF AMRITADI GUGGULU IN THE MANAGEMENT OF VATARAKTA W.S.R.TO GOUTY ARTHRITIS

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ABSTRACT

Vatarakta is one of the main articular diseases, which is characterized by severe pain, tenderness, inflammation and burning sensation in the affected joints. The aggravated *Vata Dosha* when combines with vitiated *Rakta Dhatu* may end up in an awful disease called *Vatarakta*. The etiology and symptomatology of Gout is very much similar to that of *Vatarakta*. Gouty arthritis is a disorder of purine metabolism and is inflammatory response to the MSUM (Monosodium Urate Monohydrate) crystals formed secondary to hyperuricemia. In Ayurvedic classics, although we find plenty of *dravyas* for joint disorders, the area of joint diseases management still remains to be elusive. Hence the present clinical study aims to evaluate the efficacy of *Amritadi Guggulu* in the management of *Vatarakta* (Gouty Arthritis). In the present study, 30 patients fulfilling the diagnostic criteria of *Vatarakta* were selected. Detailed profile which incorporated relevant data like symptomatology, physical signs and investigation reports were considered for assessment criteria. The *Amritadi Guggulu* was administered to patients of either sex in the dosage of 500mg BD after food for 2 months. After the course of therapy for 2 months, symptomatic improvement was observed with statistically significant results ($p < 0.001$) along with attainment of normal serum uric acid levels followed by feeling of general well-being. From the present study it can be concluded that the effect of *Amritadi Guggulu* showed promising results in the management of *Vatarakta*.

Keywords: *Vatarakta*, *Vata*, *Rakta Dhatu*, Purine, Hyperuricemia, Serum Uric Acid

INTRODUCTION

In an era when modern science is progressing with advent of advanced techniques for disease, diagnosis and treatment, there is still no easy solution for innumerable chronic difficult to treat disease. *Vatarakta* is the disorder where in pain is predominant symptom which disturbs day to day life of the patients. *Vatarakta* is an illness where both *Vata* and *Rakta* are afflicted by distinct etiological factors. The chief complaint of the patient is severe joint pain

with onset at *Hasta*, *Pada*, *Mulagata sandhi*¹ and then migrates to other joints in a way similar to *Akhuvisha*². It has been emphasized in Ayurvedic classic *charaka samhita* that specific etiological factors leads to the morbidity of the *Vata Dosha* and *Rakta Dhatu*. This vitiated *Vata dosha* along with deranged *rakta* circulates very fast all over the body due to *sukshma* (minuteness) and *drava* (liquid state) *guna* (characters) of *vata* and *rakta* respectively³,

and undergo *dosha dushya sammurchana* (pathogenesis) in *sandhi sthana* (joints), especially *pada* and *angula sandhi* (metatarso-phalangeal joint)⁴.

The condition is further aggravated by the factors like starvation and alcohol along with meat intake, which is a rich source of protein. All these conditions causes excessive breakdown of protein⁵ and purine in the body, which gets accumulated in the body. Deficiency of certain genetic factors like HGPRT causes either overproduction or underexcretion of these purine nucleotides⁶.

The condition is characterized by abnormally elevated levels of uric acid in the blood, recurring attacks of joint inflammation (arthritis), and deposits of hard lumps of uric acid in and around the joints⁷.

According to modern treatment, anti-inflammatory drugs, NSAID's glucocorticoids are used to treat Gouty Arthritis symptomatically which have many adverse effects particularly in presence of renal insufficiency and gastrointestinal disorders making the disease chronic after prolong usage. Therefore, there is a definite need to explore more efficacious and radical cure to this illness.

Hence, the present clinical study aims to evaluate the efficacy of *Amritadi Guggulu*.

Amritadi Guggulu consisting mainly of ingredients- Amrita, Guggulu, Triphala, Dantimoola, Trikatu, Vaividanga, Dalchini, Nishotha which are said to be useful in curing the illness⁸. Thus the present study was carried out with a target to hit upon a better efficacious '*Shamana Aushada*' for *Vatarakta*.

AIM OF STUDY:-

- Conceptual study of *Vata Rakta* w.s.r. to Gouty arthritis.
- To study the Etiopathogenesis of *Vata Rakta* w.s.r to Gouty arthritis in modern and ancient literature.
- To clinically evaluate therapeutic effects of *Amritadi Guggulu* in *Vata Rakta* w.s.r to Gouty arthritis.

MATERIALS AND METHODS:-

Source of Data:

A single group study trial was performed on 30 patients, who were selected from the O.P.D of the Jammu Institute of Ayurveda and Research, Department of *kaya chikitsa*. All the cases were selected on the basis of below mentioned diagnostic / inclusion and exclusion criteria. Diagnosis is made on the basis of special proforma prepared in relation to *Vata Rakta*.

Inclusion Criteria:

- a. Age in between 18 years – 70 years.
- b. Patients willing to be registered.
- c. Patients having serum uric acid concentration more than 7.0 mg/dl in males and more than 6.0 mg/dl in females.
- d. Not having any associated chronic ailment.
- e. Not having any state mentioned in exclusion criteria.

Exclusion Criteria:

- a) Age below 18 years and above 70 years.
- b) Patients not willing for trial.
- c) Patients suffering from following disorders:
- d) Rheumatoid arthritis
- e) Osteo-arthritis
- f) Diabetic, Anti T.B Drug
- g) Renal and liver disorders
- h) Obesity.
- i) Hypo-thyroidism and hyper- thyroidism.
- j) Chronic hemolytic anaemia.
- k) Auto Immune disorders
- l) Pregnant/ lactating women.

Laboratory Investigations.

- a) Serum Uric acid
- b) ESR

Design:

It is a single blind clinical study with a pre-test and post-test design. In this study 30 patients diagnosed of *Vatarakta* of either sex were subjected to clinical study.

Intervention:

Amritadi Guggulu was orally administered in a dose of 500mg BD daily after the foods for eight weeks.

Duration of Study: 60 days.

Assessment criteria:

The state of the disease *Vata Rakta* is determined by adopting the standard methods of scoring for subjective, objective and special investigation criteria, before and after the administration of drug. Score was given according to the severity of the symptoms. The symptoms score assessed and compared before and after the administration of drug, statistical analysis, and percentage of relief was used to find out the efficacy of the drug.

Subjective Criteria:

On the basis of relief in the sign and symptoms with the help of scoring pattern, Assessment of the therapy was done.

Objective Criteria:

Serum uric acid values before and after the treatment was used to assess the effect of the therapy.

The statistical analysis of these values was done before the start of the treatment, and finally after the completion of the treatment.

Subjective Criteria

Parameter	Finding	Scoring
1.Sandhi Shula	None	0
	Mild	1
	Moderate	2
	Severe	3
2.Sandhi Graha	None	0
	Mild	1
	Moderate	2
	Severe	3
3.Sandhi Shotha	None	0
	Mild	1
	Moderate	2
	Severe	3
4.Vaivarnya	None	0
	Mild	1
	Moderate	2
	Severe	3
5.Sparshasahatvata	None	0
	Mild	1
	Moderate	2
	Severe	3

CRITERIA FOR THE TOTAL EFFECT OF THERAPY

For the assessment of the total therapy following four categories were taken into considerations.

Cured – 76% to 100%

- Complete relief in subjective signs and symptoms.

Markedly Improved -51% to 75%

- Relief in subjective signs and symptoms.

Improved – 26% to 50%

- Relief in sign and symptoms.

Unchanged- up to 25%

- Relief in some subjective sign and symptoms only.

30 patients suffering from *Vatarakta* (hyperuricemia/ Gouty arthritis) were selected according to the inclusion and diagnostic criteria. The drug was administered for a period of two months. The descriptive statistical analysis of the whole sample is divided into two sections as demographic data and data related to disease stated as below:

DATA

Table 1: Distribution of patients according to age

Serial No.	Age group	No. of patients	Percentage
1.	21-30	3	10 %
2.	31-40	3	10 %
3.	41-50	17	56.66 %
4.	51-60	7	23.33 %

Table 2: Showing distribution of patients according to sex

Sex	No. of patients	%age
Male	21	70%
Female	9	30%

Table 3: Distribution according to the Religion

Religion	No. of patients	Percentage
Hindu	22	73.33%
Muslim	1	3.33 %
Sikh	7	23.33%

Table 4: Distribution according to the marital status

Marital status	No. of patients	Percentage
Married	29	96.66%
Unmarried	1	3.33%

Table 5: Distribution according to the socio-economic status

Socio-economic status	No. of patients	Percentage
Poor	0	0
Lower middle class	6	20 %
Middle class	24	80 %
Upper	0	0

Table 6: Distribution according to the profession

Occupation	No. of patients	Percentage
Agriculture	6	20 %
Business	10	33.33 %
Service	5	16.66%
Housewife	9	30%

Table 7: Distribution according to the *deha prakriti*

<i>Deha prakriti</i>	No. of patients	Percentage
<i>Vataj</i>	0	0 %
<i>Pittaj</i>	0	0%
<i>Kaphaj</i>	0	0 %
<i>Vata-pitta</i>	16	53.33 %
<i>Vata-kapha</i>	5	16.66 %
<i>Pitta-kapha</i>	9	30 %
<i>Tridoshaj</i>	0	0 %

Table 8: Showing distribution according to the dietary habits.

Dietary habits	No. of patients	Percentage
Veg	6	20 %
Mixed	24	80 %

Table 9: Distribution according to the initial involvement of Joint

Initial Joint	Total Patients	Percentage
Big Toe	18	60.00%
Metatarsal Joints	5	16.67%
Ankle	4	13.33%
Knee	3	10.00%

CLINICAL RESULTS

Table 10: Effect of *Amritadi Guggulu* on *Sandhi Shoola*.

Mean		d	%	S.D.	S.E	t	P
BT	AT						
4.43	1.47	2.96	66.81	2.63	0.48	6.17	<0.001

The initial score of *sandhi shoola* on average was 4.43 which came down to 1.47 after the improvement on average was found to be 66.81 %. Here

$p < 0.001$ which indicates that during the trial the drug is highly significant on *Sandhi shoola*.

Table 11: Effect of *Amritadi Guggulu* on *Sandhi Shotha*.

Mean		D	%	S.D.	S.E	T	P
BT	AT						
1.93	0.73	1.2	62.06	.40	0.074	17.1	<0.001

The initial score of *sandhi shotha* on average was 1.93 which came down to 0.73. The improvement on average was found to be 62.06 %. Here $p < 0.001$

which indicates that during the trial the drug is highly significant on *Sandhi shotha*.

Table 12: Effect of *Amritadi Guggul* on *Sandhi Graha*

Mean		d	%	S.D.	S.E	t	P
BT	AT						
1.73	0.73	1	57.61	.37	0.06	16.6	<0.001

The initial score of *sandhi Graha* on average was 1.73 which came down to 0.73 the improvement on average was found to be 57.61%. Here $p < 0.001$

which indicates that during the trial the drug is highly significant on *sandhi Graha*.

Table 13: Effect of *Amritadi Guggulu* on *Vaivranata*

Mean		d	%	S.D.	S.E	T	P
BT	AT						
1.8	0.8	1.0	54.5	.4	0.07	14.3	0.001

The initial score of *vaivranata* on average was 1.8 which came down to 0.8. The improvement on average was found to be 54.5 %. Here $p < 0.001$ which

indicates that during the trial the drug is highly significant on *vaivranata*.

Table 14: Effect of *Amritadi Guggulu* on *Sparshasahatvata*

Mean		d	%	S.D.	S.E	T	P
BT	AT						
1.53	0.7	0.8	53.3	0.82	0.15	5.3	0.001

The initial score of *Sparshasahatvata* on average was 1.53 which came down to 0.7. The improvement on average was found to be 53.3%. Here $p < 0.001$

which indicates that during the trial the drug is highly significant on *Sparshasahatvata*.

Table 15: Effect of *Amritadi Guggulu* on Serum uric acid

Mean		d	%	S.D.	S.E	t	P
BT	AT						
9.4	4.4	5.0	53.23	.64	0.11	25.0	<0.001

The mean Serum Uric acid level before and after treatment on average was 9.4 and 4.4 respectively. The change on average was 53.23%. Here $p < 0.001$

which indicates that the drug has highly significant effect on Serum Uric acid levels.

Table 16: Effect of *Amritadi Guggulu* on ESR.

Mean		d	%	S.D.	S.E	t	P
BT	AT						
17	11.2	5.8	51.78	6.15	0.12	7.08	<0.001

The mean ESR level before and after treatment on average was 17 and 11.2 respectively. The change on average was 51.78%. Here $p < 0.001$ which indicates that the drug has highly significant effect on Serum Uric acid levels.

Nidana is one of the main treatment aspects, mainly *Ahara Hetu, Vihara Hetu, Anya Hetu* and *Mithyahara Vihara* which are known to be responsible in the manifestation of disease *Vatarakta*. Clinical varieties of *Vatarakta* are also elaborated according to the association of vitiated *dosha* in the primary pathology of *vata* and *rakta* and are named as *Vatadhika vatarakta, Pittadhika vatarakta, Kaphadhika vatarakta* and *raktadhika vatarakta*.

So many remedies are mentioned for the management of *Vatarakta* i.e. *Raktamokshana, Basti, Virechana, Shamanaushadhi* and *Nidana Parivarjana* etc.

During the trial study in which 30 patients selected from the OPD of the Jammu Institute of Ayurveda & Research, Nardani, Jammu, following observations were noticed.

DISCUSSION

Vatarakta is one of the unique disorders among the *vatavyadhi*. Compared with other *vatavyadhi, vata Rakta* possesses a special place in the society, due to its high prevalence in the society, and increased incidence as age advances and so on.

Dietary habits and life style modalities plays a major role in the manifestation of *Vatarakta*. Habitual intake of food stuffs is always useful but improper way of consuming makes always harmful to the body. Therefore they should be avoided always.

- 1. Age:** In this study among the total 30 patients maximum patients were in the age group of 41-50 (56.66 %) and 51-60 (23.33 %). This indicates that this disease *vatarakta* usually occurs in the later stages i.e 4th and 5th decade of the life.
- 2. Sex:** In this study 70% i.e. 21 number of patients were male and the remaining 30 % i.e 9 patients were females. It is suggestive of the fact that *vatarakta* is more seen in male patients. The probable reason may be disturbed dietary habits, stress and comparatively more journey.
- 3. Religion:** A maximum number of patients 73.33 % i.e 22 patients were hindu, 23.33 % i.e 7 patients were sikh, and 3.33 % i.e 1 patient belonged to muslim community. The dominance of the disease among the Hindus represents only that the area from which samples are taken is Hindu dominant. To determine the exact incidence of ratio, community wise dominated areas should be screened and overall ratio should be determined.
- 4. Marital Status:** Incidence about marital status indicates that maximum number of patients i.e. 96.66 % i.e. 29 patients were married and only 3.33 % i.e. 1 patient was unmarried. Based on the marital status nothing can be concluded about the disease.
- 5. Socio-economic status:** The incidence about socio-economic status indicates that maximum 80 % i.e. 24 patients belonged to middle class, 20 % i.e. 6 patients were from lower middle class.
- 6. Profession:** The study reveals that maximum number of patients 33.33 % i.e. 10 patients were of business class, 16.66 % i.e. 5 patients were in services, 20 % i.e 6 patients were doing agriculture, and 30 % i.e 9 patients were housewives. The incidence of *vatarakta* is more common in people following sedentary lifestyle and lack of exercise. That is why it has been also named as *khudvata*.
- 7. Dietary habits:** The incidence about dietary habits shows that maximum 80% i.e 24 patients were taking mixed diet, 20% i.e 6 patients were taking vegetarian diet. Taking *mamsa* is a causative factor for *vatarakta* as mentioned in the ayurvedic classics, as it is rich in protein content.
- 8. Deha Prakriti:** A maximum number of 53.33 % i.e 16 patients were of *vata-pitta prakriti*, 30 % i.e 9 patients were of *pitta-kapha prakriti*, 16.66 % i.e 5 patients were of *vata-kapha prakriti*.
- 9. Affected Joint:** A maximum 60.00% i.e. 18 patients were affected at big toe, 16.67 % i.e 5 patients were affected at the metatarsal joint, 13.33 % i.e 4 patients were affected at ankle joint, 10% i.e. 3 patients were affected at knee joint. According to the classics, *pada* is the foremost and most commonly affected joint in *vatarakta*.

PROBABLE MODE OF ACTION OF DRUG

The management of hyperuricemia goes through two ways:

1. Management of Symptoms
2. Breaking down the Pathology- this comprises of two set of medications:
 - I. Inhibition of Xanthine Oxidase-Xanthine Oxidase inhibitors decrease the production of Uric Acid by interfering with Xanthine Oxidase enzyme⁹.
 - II. Excretion of Uric acid through Uricosurics¹⁰- Uricosurics increases the excretion of uric Acid by reducing its re-absorption once the kidneys have filtered it out of the blood.

The effect of trial drug *Amritadi Guggulu* is due to anti-inflammatory¹¹ activity of *Amrita* which reduces the inflammation and gives symptomatic relief as well as its uricosuric action which excretes excess amounts of Uric Acid from the body. *Amrita* also works on the other associated symptoms of the disease like fever and stone forming tendencies¹². Another important content of *Amritadi Guggulu* is *Guggulu* which possesses the properties of anti-inflammatory, antioxidant, Uricosuric; anti-rheumatoid helps in breaking the patho-physiology of Gout¹³. *Triphala* works as a Xanthine Oxidase inhibitor¹⁴ like Allopurinol which suppresses the production of Uric Acid. Its content *Haritaki* has antioxidant and adaptogenic properties which help in the recovery and healing of deformed tissue. *Bibhitaki*, another content of *Triphala* has nephro-protective function which retards the Urolithiasis and dissolves already formed stones in kidney while *Amalaki* has anti-inflammatory, analgesic, antipyretic and antioxidant properties which help reducing the local and systemic inflammatory effects of Gout.

Vaividanga with its antioxidant property brings out the regenerative changes in the deformed joints due to hyperuricemia induced Gout¹⁵. *Maricha* has Anti-oxidant, immune-modulatory property subsides the hyperactive immune responses precipitated due to Uric Acid. Vasodilatory property increases the blood circulation to the affected joint and enhances the process of phagocytosis of antigen-antibody complexes responsible for hypersensitivity which gave rise to inflammation. *Trivritta* and *Danti* possess anti-inflammatory and immunomodulatory properties respectively which help in alleviating the symptoms of the disease and combating the hyper-immune responses¹⁶. Also, *Danti* possesses antioxidant property which helps in the rejuvenation of the joint along with breaking the pathology of the disease.

In this way, *Amritadi Guggulu* has all the aspects of Pharmaco-therapeutic effect required for the management of Hyperuricemia induced Gout like Anti-inflammatory, Anti-oxidant, Immuno-modulator, Xanthine Oxidase Inhibitor, Uricosuric and Diuretic effects. *Amritadi Guggulu* as a compound formulation contains the drugs which have multi directional effect on the management of Gout. Hence, it has shown highly significant results in the management of the disease. As per the properties of drugs in *Amritadi Guggulu*, it also has preventive effect in Gout.

CONCLUSION

The study shows that as described in ancient *Ayurveda* literature *Vata-rakta* is a disease characterised by pain, burning, swelling, and itching at particular site of the joints especially in meta-tarso-phalangeal joint and knee joints which is also described in case of Gout by contemporary literature. *Vata-rakta* is purely *Shakha-gata* disease which is caused by vitiation of *Vata* with disordered property of *Rakta* hence it is called *Vata* and *Rakta-vikara*. *Amritadi Guggulu* has significant effect on the symptoms of *Vata-rakta* as described in our texts and this study has proved the same. *Amritadi Guggulu* also has very significant effect on the level of serum uric acid, which is a

prominent marker of diagnosis and prognosis of *Vata-rakta* with special reference to Gouty Arthritis.

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