

Clinical Evaluation of V.H.V. and *Simhanadaguggulu* in *Amavata* (Rheumatoid Arthritis)

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Amavata (Rheumatoid arthritis) is a chronic, degenerative disease of connective tissue mainly involving joints. Two groups of Ayurvedic preparations were evaluated as a possible remedy for the disease. One hundred and thirty five patients were divided into three separate groups. First group received V.H.V. (500 mg. tds - po) a combination of three ingredients i.e., Vettumaran gutika, Hari-dradi and Vacadi ganas (90 patients). Second group received *Simhanadaguggulu* (1 g. with 9 ml. Castor oil bds—po-25 patients) and the third group served as control. It was given starch tablets 500 mg. bds (.0 patients). Duration of the trial was 90 days. Improvement after therapy was graded as per the criteria of American Rheumatism Association. Signi-

fiant clinical improvement was noted in group I and II. (X^2 test, $P < 0.001$ for group I and $P < 0.02$ for group II in comparison to group III). E.S.R. also significantly decreased in these groups. However, no increase in haemoglobin percentage was noted.

The result of the study clearly shows that V.H.V. combination and *Simhanadaguggulu* can be used as effective remedies for rheumatoid arthritis.

Introduction

Swelling and pain in multiple joints are the main features of *Amavata* (rheumatoid arthritis). Constant use of incompatible food articles, strenuous exercise immediately after fatty food lead to indigestion resulting in the formation of *Ama* and the *Ama* gets circulated throughout the body by *Vyanavayu* (Madhavakara) and accumulates at *Slesmasthanam* especially of *Slesakakapha*

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(Vagbhata), i.e. in the joints leading to the manifestation of symptoms of the disease. Body pain, loss of appetite, fever, weakness, excessive thirst and heaviness of the body are also present in this disease. Involvement of joints restricts the movement which may lead to contracture of muscles and permanent deformities (Hollander, 1966). Blood investigation will show a high E.S.R. and positive R.A. factor in 30 to 40% of cases. Prognosis of *Amavata* is poor especially in these cases where *Tridosas* are equally involved (Madhavakara). In view of its widespread prevalence and chronic nature, it was thought worthwhile to find out an effective remedy to this disease, hence this clinical trial.

Materials and Method

One hundred and thirty five *Amavata* patients were selected from Out Patient Department of the Institute and grouped into three at random. First group was treated with a compound preparation comprising of (a) *Vacadigana* (b) *Hari-dradigana* (Vagbhata) and (c) *Vettumaran* pills (Vaidyan and Pillai, 1969) and the second group was treated with *Simhanadaguggulu* (Shastri, 1969). The third group was treated with placebo and kept as control. Ninety cases continued till the end of the trial in group I whereas only twenty five cases did so in group II and twenty cases in group III. The dropouts were due to subsequent complications. As *Simhanadaguggulu* contains

good quantity of *Eranda taila*, many patients receiving it reported loose motion and could not complete the trial. One pill of 500 mg. thrice daily was fixed as an adult dose in group I and III. 1 g. *Simhanadaguggulu* pill with 9 g. castor oil was prescribed thrice daily in group-II and minimum period of treatment was fixed as ninety days. Criteria for selection was fixed as prescribed by American Rheumatism Association i.e., morning stiffness, pain on motion or tenderness in atleast one joint, swelling in atleast one joint continuously for not less than six weeks, swelling of atleast one other joint, symmetrical joint swelling with simultaneous involvement of the same joint on both sides of the body, subcutaneous nodules over bony prominence on extensor surface or in juxta articular region (this is evidenced only in very few cases) X-ray changes typical of rheumatoid arthritis and positive sheep cell agglutination test—this is not found in all the cases. The Institute is not having facilities for synovial biopsy to study histological changes and synovial fluid aspiration. Haemoglobin estimation, E.S.R., total leucocyte count, differential leucocyte count and V.D.R.L. test were also done wherever found necessary. The investigations were repeated once every month and at the end of the trial. Periodical clinical improvement was assessed and recorded. The criteria given in the Annexure I and II was followed for assessing the improvement. Seventy

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per cent of the patients were females and about 50% of the cases were in the age group of 19-44 years (Table-I). Result of the treatment was graded as complete relief, partial relief, mild relief and no relief.

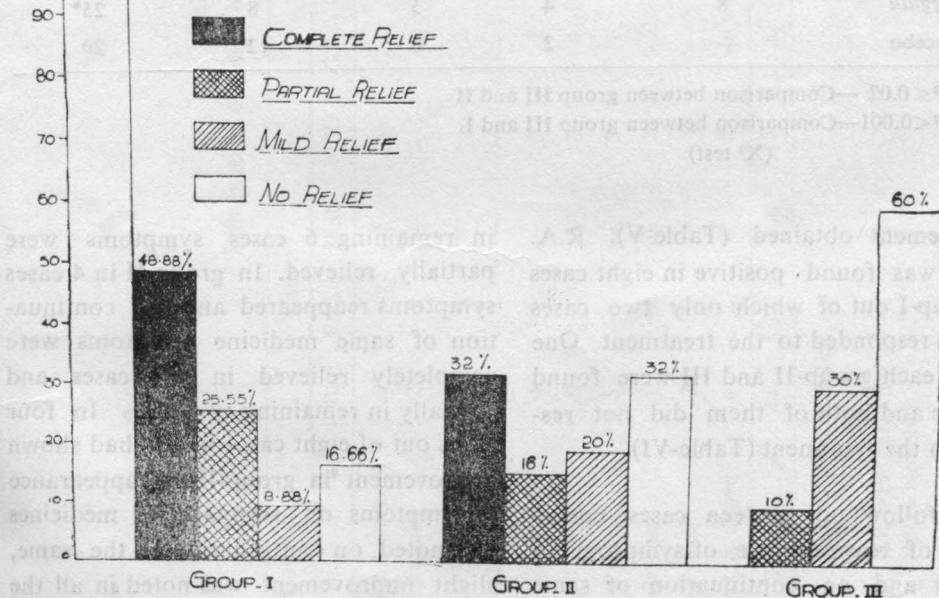
Result

Forty four cases reported complete relief of symptoms, partial relief was noted in twenty three cases and mild relief in eight cases in group-I. Complete relief in eight cases, partial relief in four cases and mild relief in five cases was noted in group-II. Partial relief in two cases and mild relief in six cases was

noted in group-III. Fifteen cases in group-I, eight cases in group-II and twelve cases in group-III did not respond to the treatment. (Fig.).

The results in group I and II were statistically significant in comparison with group-III. The result in group-I was highly significant whereas in group II it was just significant (Table-II). The relief obtained in chronic cases of more than five years duration was poor in all the groups (Table-III). Reduction of E.S.R. was significant and proportional to corresponding clinical improvement noted (Table-IV). Haemoglobin percentage did not improve corresponding to the clinical

RESULT OF TREATMENT



Showing the effect of treatment in three different groups of patients

Table—I
Age, Sex and Community wise classification of patients

Age group	Hindu		Muslim		Christian		Total
	M	F	M	F	M	F	
6—12 years	2	2	4	2	—	1	11
13—18 years	9	4	4	2	2	—	21
19—44 years	6	34	5	11	2	8	66
45—64 years	3	24	3	2	—	4	36
65 years and above	—	1	—	—	—	—	1
Total	20	65	16	17	4	13	135

Table - II
Result

Group	Complete relief	Partial relief	Mild relief	No relief	Total
I V.H.V.	44	23	8	15	90**
II Simhanada-guggulu	8	4	5	8	25*
III Placebo	—	2	6	12	20

* P<0.02 —Comparison between group III and II

** P<0.001—Comparison between group III and I
 $(X^2$ test)

improvement obtained (Table-V). R.A. factor was found positive in eight cases in group-I out of which only two cases slightly responded to the treatment. One case in each group-II and III were found positive and both of them did not respond to the treatment (Table-VI).

On follow up thirteen cases complained of reappearance of symptoms in group I and on continuation of same medicines 7 cases showed complete relief,

in remaining 6 cases symptoms were partially relieved. In group II in 4 cases symptoms reappeared and on continuation of same medicine symptoms were completely relieved in two cases and partially in remaining two cases. In four cases out of eight cases which had shown improvement in group-III, reappearance of symptoms on stoppage of medicines was noted, on continuation of the same, slight improvement was noted in all the cases (Table-VII).

Table - III
Influence of duration of disease on relief obtained

Duration	Group I				Group II				Group III			
	C.R.	P.R.	M.R.	N.R.	C.R.	P.R.	M.R.	N.R.	C.R.	P.R.	M.R.	N.R.
Upto 1 week	5	4	1	—	—	—	—	—	—	1	—	2
1—2 weeks	2	2	—	—	—	—	—	—	—	—	1	—
2—4 weeks	7	4	—	—	2	—	1	—	—	—	1	2
4—12 weeks	6	2	—	—	—	—	—	—	—	1	1	1
12—24 weeks	4	1	—	2	1	1	1	1	—	—	—	1
6M—1 yr.	8	5	1	3	4	1	2	3	—	—	2	2
1—2 years	5	—	—	2	1	—	—	1	—	—	—	—
2—3 years	1	—	1	2	—	2	1	—	—	—	—	2
3—5 years	2	3	—	1	—	—	—	—	—	—	—	—
5 yrs. & above	4	2	5	5	—	—	—	3	—	—	1	2
Total	44	23	8	15	8	4	5	8	—	2	6	12

C.R.=Complete relief

M.R.=Mild relief

P.R.=Partial relief

N.R.=No relief

Table—IV
Effect of V.H.V. and Simhanadaguggulu on E.S.R. in *Amavata* patients
E.S.R. (mm./hr)

	Complete relief patients			Partial relief patients			Mild relief patients			No relief patients		
	Initial	2nd month	3rd month	Initial	2nd month	3rd month	Initial	2nd month	3rd month	Initial	2nd month	3rd month
I. V.H.V.	60.91 ± 4.13	42.14* ± 5.57	13.15** ± 0.88	62.13 ± 4.86	43.00** ± 3.78	28.57** ± 1.22	78.13 ± 9.02	66.67 ± 7.93	54.86 ± 4.40	73.67 ± 7.61	75.00 ± 7.25	74.00 ± 4.81
II. Simhanada-guggulu	55.63 ± 9.18	32.60* ± 3.70	16.63** ± 1.60	51.00 ± 15.13	48.25 ± 8.82	27.00** —8.00	26.75 ± 10.56	94.80** ± 12.16	56.75 ± 18.45	90.25 12.58	67.14 ± 17.52	90.25 ± 5.24
III. Placebo	—	—	—	62.50@	60.00	37.50	75.83 ± 5.34	65.00 ± 6.13	60.00@ ± 2.89	90.17 ± 4.76	86.50 ± 4.35	87.24 ± 3.46

* P<0.05

** P<0.01 (Paired 't' test)

@ Two patients only

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Table—V
Effect of V.H.V. *Simhanadaguggulu* on Haemoglobin percentage in *Amavata* patients Hb.%

Group	Initial	2nd month	3rd month
I. V.H.V.	72.86 ± 2.53	66.06 ± 3.06	69.69 ± 1.96
II. <i>Simhanadaguggulu</i>	73.71 ± 1.97	74.06 ± 2.20	74.29 ± 2.00
III. Placebo	71.25 ± 1.15	71.90 ± 1.35	69.25 ± 0.91

Table—VI
No. of R.A. positive cases in each group

Group	Total No. of cases	No. of R.A. positive cases	Mild relief	No relief
I	90	8	2	6
II	25	1	—	1
III	20	1	—	1

Table—VII
Follow up data after stoppage of Medication

Group	No. of cases responded to treatment	Relapse of symptom noted	Response to further treatment
I	75	13	Complete relief in 7 cases Partial relief in 6 cases
II	17	4	Complete relief in 2 cases Partial relief in 2 cases
III	8	4	Mild relief in 4 cases

Discussion

Agnimandya and *Ama* are mainly responsible for this disease. Hence all the efforts are directed towards improving the *Jatharagni* which is expected to give good response in *Amavata*. For the improvement of *Jatharagni* and for digestion of *Ama*, *langhana* (fasting) and *deepanopachana* and *tikta* (bitter) *rasa* predominant drugs and diet are recommended (Sastri, 1969 and Warrier). It is obvious that all the ingredients in V. H. V. possess *Laghu*, *Usna*, *Ruksa* and *Dipanapacana* properties and could be responsible for the better results in this group. In *Simhanadaguggulu*, consisting *Erandataila*, *Guggulu*, *Gandhaka* and *Triphala*, *Eranda taila*, is recommended as a specific for *Amavata* (Bhavamisra, 1961) and *Guggulu* is well known for its anti-inflammatory activity. *Gandhaka* is also a well-known drug for treatment of inflammatory conditions and *Triphala* has *tridosahara* and anti-inflammatory properties. Though relief obtained with *Simhanadaguggulu* was significant, yet, due to the purgative action of *Eranda taila*, the drug is not agreeable to many patients.

It is suggested that usefulness of the drug can be improved by reducing the *Eranda taila* content to reduce incidence

of purgation. It would be interesting and useful to interpret the data on the basis of modern concept of Rheumatoid arthritis and efforts should be made to find out the mechanism of anti-arthritis activity found in the above groups of drugs. Apart from purgation in some cases in Group-II no adverse effect due to drug therapy was noted in any of the groups.

Conclusion

Two compound Ayurvedic preparations of *V.H.V.* and *Simhanadaguggulu* were found effective in *Amavata*, and the result obtained with *V.H.V.* was highly significant, hence it can be effectively employed in the treatment of *Amavata*.

Acknowledgement

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हिन्दी सारांश

**आमवात रोग में सिहनाद गुणगुलु एवं वी. एच. वी. का निदान चिकित्सात्मक मूल्यांकन
पी. रामचन्द्रन नायर, एन. पी. विजयन एवं पी. माधविकुट्टी**

आमवात, प्रायः सन्धिगत क्षीयमाण श्लेषक कफ और पेशीकण्डराओं का एक दीर्घकालिक रोग है। आयुर्वेदीय औषधियों का दा वर्ग के रोगियों में निदान-चिकित्सात्मक अध्ययन किया गया।

135 रोगियों को तीन वर्गों में बाटा गया। पहले वर्ग के 90 रोगियों को वी. एच. वी., की 500 मि. ग्रा. की वटिकाएं (बेट्टूमारन गुटिका, हरिद्रादि और वचादि गण का मिश्रण) दी गई। दूसरे वर्ग के 25 रोगियों को सिहनादगुणगुल 1 ग्रा. 9 मि. लि. एरण्ड तैल के साथ दो बार दिया गया एवं तीसरे वर्ग के 20 रोगियों को (नियंत्रित वर्ग) स्टार्च वटिकाएं (500 मि. ग्रा.) दी गई।

चिकित्साकाल 90 दिन का था। चिकित्सा के बाद अमेरिकी आमवात रोग संघ के मानदण्ड के आधार पर सांख्यिकीय विश्लेषण किया गया। उल्लेखनीय चिकित्सा लाभ पहले व दूसरे वर्ग में मिला। (वर्ग-तीन की तुलना में वर्ग-एक में काई² परीक्षण, पी <0.001 एवं वर्ग दो में पी <0.02)। इन वर्गों में ई. एस. आर. भी गणनीय रूप में कम हुआ। लेकिन हीमोग्लोबिन की वृद्धि नहीं देखी गई।

इस अध्ययन के परिणाम से सिद्ध होता है कि वी. एच. वी. सम्मिश्रण और सिहनादगुणगुल आमवात की चिकित्सा में उपयोगी है।

Semi-Quantitative Criteria for Estimating Degree of Disease Activity
(American Rheumatism Association Committee on Diagnostic and Therapeutic Criteria)

Grade	0	1	2	3
Subjective				
Morning stiffness	5 minutes or less	5 minutes to two hours	2 to 8 hours	8 hours or more
Fatigue	None	Works full time despite some fatigue	Patient must interrupt work to rest	Fatigued at rest
Pain	None	On motion only	At rest	Wakes patient from sleep
Patient's estimate	Fine	Almost well	Pretty good	pretty bad
II Functional				
General function	Full activity without difficulty	Most activities but with difficulty	Few activities, cares for self	Little self care, mainly chair and bed
Grip strength	200 mm. Hg. or more	195 to 120	115 to 70	Under 70 mm.
Objective				
Spread of joint involvement	None	0 to 50	51 to 100	over 100
Westergren sed. rate	0 to 20 mm.	20 to 40	41 to 70 mm.	71 mm. or more
Haemoglobin	12.5 gm. or more	12.4 to 11 gm.	10.9 to 9.5 gm.	Less than 9.5 gm.
Physician's estimate	Inactive	Minimally active	Moderately active	Severely active

Criteria for assessment

Grade - I : Complete remission/Complete relief

- *1. No systemic signs of rheumatoid activity
- *2. No signs of joint inflammation
- *3. No evidence of activity in any extra-articular process including nodules, tenovaginites and irites.
- *4. No remaining impairment of joint mobility other than that associated with irreversible changes.
- *5. No elevation of E.S.R.
- *6. Articular deformity or extra articular involvement due to irreversible changes may be present.

Grade - II : Major improvement—Partial relief

- *1. No systematic signs of rheumatoid activity, with exception of an elevated sedimentation ratio and vasomotor imbalance.
- *2. Major signs of inflammation resolved, such as heat redness of joints and of extra articular involvement.
- *3. No new rheumatoid process of intra articular or extra articular structures.
- *4. Minimum joint swelling may be present.
- *5. Impairment of joint mobility associated with minimum residual activity may be present.
- *6. Articular deformity of extra articular involvement due to irreversible changes, may be present.

Grade - III : Minor improvement/mild relief

Any decrease in signs of rheumatoid activity inadequate to fulfill and criteria of Grade II.

- *1. Diminution of systemic signs of rheumatoid activity.
- *2. Signs of joint inflammation only partially resolved.
- *3. No evidence of extension of rheumatoid activity into additional articular or extra articular structures.

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- *4. Decreased but no minimum joint swelling present.
- *5. Impairment of joint mobility due to residual inflammation to present.
- *6. Articular deformity or extra articular involvement due to irreversible changes may be present.

Grade—IV : Unimprovement or Progression/No relief

- *1. Undiminished signs of rheumatoid activity regardless of functional capacity.
- *2. Exacerbation of any previously involved joint or joints or development of sites of rheumatoid activity.
- *3. Roentgenologic changes indicative of progression of the Rheumatoid process excepting hypertrophic changes.
- *4. In the presence of one or more of the aforementioned criteria improvement in other features including a normal or lowered erythrocyte sedimentation rate, not significant.

* Items which must be present for each grade.