

A clinical study on the management of Amavata (Rheumatoid arthritis) with Simhanada guggulu and Alambushadi churna tablet

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ABSTRACT : In this clinical study, 90 patients of Amavata (Rheumatoid arthritis) were registered from the O.P.D. & I.P.D., Deptt. of the Kayachikitsa, I.P.G.T. & R.A., G.A.U., Jamnagar. In Group-A, 40 patients completed the treatment out of 44 patients and 4 patients left the treatment before completion of the course and the treatment schedule was :- Alambushadi churna 4 tablets orally thrice daily with warm milk for 45 days (Each tablet containing 500mg Alambushadi churna) along with 1gm Simhanada guggulu orally thrice daily with warm water for 45 days and Shatapushpadi lepa applied locally over affected joints with warm water for 45 days. In Group-B, 40 patients completed the treatment out of 46 patients and 4 patients left the treatment before completion of the course. The treatment schedule was : Simhanada guggulu & Shatapushpadi lepa both given in same dose & duration as in Group-A. In Group-A maximum patients i.e. 65 % showed major improvement, while in Group-B maximum patients i.e. 50 % showed minor improvement. No side effects of the research drugs were observed during the clinical trial. Group-A therapy is more effective than Group-B therapy in this clinical study.

Key words : Amavata, Rheumatoid arthritis, Alambushadi churna tablets, Simhanada guggulu, Shatapushpadi lepa.

INTRODUCTION

Nowadays the change of life style, diet habit and chronic physical and mental stress of human being plays a major role in the manifestation of several disorders. Thus, that type of pattern may also lead to the development of the disease Amavata. In Ayurveda, Madhava kar (700AD) mentioned first 'Amavata' as a special disease entity, where Ama as well as Vata plays a predominant role in the pathogenesis or samprapti of this disease¹. According to the clinical manifestations, the disease Amavata very closely resembles with the Rheumatoid arthritis, which is a chronic but active inflammatory arthropathy as per modern medical science. It is chronic in nature and affects mostly the middle aged females. The disease Amavata or Rheumatoid arthritis is a most remarkable problem in the society in modern era. The suitable effective treatment of this disease is not available in the modern medicine till now. The national economy is badly affected due to this disease problem as the young aged people are mostly affected by this disease and the patients are gradually crippled both physically and psychologically regarding to the worst prognosis of this disease. So it draws a major attention nowadays to different scholars for research purpose.

Aims & Objectives :

1) To ameliorate the clinical features of Amavata and increase the work ability. 2) To minimize the periodic fluctuation of the disease. 3) To assess the effect of the selected drugs on Amavata or Rheumatoid arthritis. 4) To evaluate the role of selected drugs on Amavata or Rheumatoid arthritis.

MATERIALS AND METHODS

Total 90 patients fulfilled the criteria for the diagnosis of the disease Amavata (Rheumatoid arthritis) and were registered for the present clinical study irrespective of their sex, religion, etc. Among them, 10 patients were dropped out from the treatment before the completion of the therapy. The patients were selected from the O.P.D. & I.P.D. of Dept. of Kayachikitsa of I.P.G.T. & R.A., Gujarat Ayurved University, Jamnagar.

Inclusion criteria :

- 1) Patients between 18 to 60 years age.
- 2) The patients having the clinical features of Amavata according to Ayurvedic classics like Angamarda, Aruchi, Gaurava, Trishna, Jwara, Shula, Shotha etc. were selected for the present clinical research work. The detailed research proforma was prepared incorporating all the clinical features seen in the disease Amavata (Rheumatoid arthritis).

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- 3) The patients who had fulfilled the revised criteria for Rheumatoid arthritis fixed by the American College of Rheumatology in 1987.

Exclusion criteria :

Sandhigatavata (Osteoarthritis), Vatarakta, Rheumatic arthritis, Septic arthritis, Gouty arthritis, Psoriatic arthritis, SLE (Systemic lupus erythematosus), Cardiac problems, Diabetes Mellitus, Tuberculosis, Thyroid disorders, HIV, Hepatitis and any Malignancy & having age below 18 years and above 60 years.

The disease was diagnosed on the basis of signs and symptoms as described in Ayurvedic and Modern texts, aided by the revised criteria for Rheumatoid arthritis fixed by the American College of Rheumatology in 1987. R. A. factor and C-Reactive Protein investigations had been done in all the patients for diagnosis and severity of the disease. Routine Blood, Urine and Stool examinations along with Serum uric acid and Fasting Blood Sugar had been also done to rule out other pathological conditions of the registered patients.

Plan of Study :

The selected patients were randomly divided into following two groups.

A) In Group-A, out of registered 44 patients 40 patients completed the treatment and 4 patients left the treatment before completion of the course. The applied treatment schedule in Group-A was:- 4 tablets of Alambushadi Churna (B.P. 26/69-70) were given orally thrice daily with warm milk for 45 days (Each tablet containing 500mg Alambushadi Churna)³, 1gm Simhanada Guggulu (B.R. 29/185-190) was given orally thrice daily with warm water for 45 days⁴, and Shatapushpadi Lepa (B.R. 29/9-10) was applied locally over affected joints with warm water for 45 days⁵.

B) In Group-B, out of registered 46 patients 40 completed the treatment and 4 patients left the treatment before completion of the course. The applied treatment schedule in Group-B was :- 1gm Simhanada Guggulu was taken orally thrice daily with warm water for 45 days, Shatapushpadi Lepa was applied locally over affected joints with warm water for 45 days.

All the above medicines were referred from Amavatarogadhikara of Ayurvedic classics like Bhaishajya Ratnavali (B.R.) and Bhava Prakasha (B.P.).

Criteria for Assessment :

The results of the therapy were assessed on the basis of clinical features of the disease Amavata, which

are mentioned in Ayurvedic classics as well as with the help of criteria fixed by American Rheumatology Association in 1988. The scoring pattern adopted for assessment of clinical features are as follows:

Sandhishula (pain in joint) :	Score
(a) No Pain	00
(b) Mild Pain	01
(c) Moderate pain but no difficulty in moving	02
(d) Slight difficulty in moving due to pain	03
(e) Much difficulty in moving the bodily parts	04
Sandhishotha (Swelling in joints) :	
(a) No Swelling	00
(b) Occasional swelling	01
(c) Swelling present for the particular time of the day	02
(d) Persisting swelling	03
Sparsha-asahyata (Tenderness over joints) :	
(a) No tenderness	00
(b) Subjective experience of tenderness	01
(c) Wincing of face on pressure	02
(d) Wincing of face with withdrawal	03
(e) Resist to touch	04
Sandhi stabdhata (Stiffness of joints) :	
(a) No Stiffness or stiffness Lasting for less than 1 hour.	00
(b) Stiffness lasting for 1 hour to 2 hours.	01
(c) Stiffness Lasting for 2 hours to 8 hours.	02
(d) Stiffness Lasting for more than 8 hours.	03
Other clinical features of Amavata :	
Like Angamarda, Aruchi, Trishna, Alasya, Gaurava, Jwara & Apaka	
(a) Symptoms observed before treatment	03
(b) Some relief after treatment	02
(c) More relief after treatment	01
(d) Complete relief after treatment	00
(e) No improvement after treatment	03

Functional Assessment :

a) Walking time : The patients were asked to walk a distance of 30 feet and the time taken was recorded before and after the treatment by using stop watch. b) Grip Strength : To measure the functional capacity of the affected upper limb, especially for both hands and wrist joints, the patients ability to compress an inflated ordinary sphygmomanometer cuff under standard conditions (i.e 20 mmhg) was recorded before and after the treatment. c) Foot pressure : To measure an objective view of the functional capacity of the affected leg, especially affected ankle and metatarsophalangeal joints, foot pressure was recorded by the ability of the patients to press a weighing machine.

Overall Assessment of the Therapy :

To assess the overall effect of the therapy, the criteria collected from ARA (1988) and it was implemented in this clinical study. Results were classified into four categories as follows: a) Complete Remission, b) Major Improvement, c) Minor Improvement, d) No improvement.

OBSERVATIONS

Maximum numbers of patients i.e. 62.22 % belonged to 31 - 50 years of age group. The 83.33% patients were female, 84.44 % patients were hindu (As, Jamnagar is Hindu majority area), 97.78 % patients were married, 70.00 % patients were housewives (As, Maximum patients were middle aged female), 58.89 % were from middle class, 73.33 % were in urban habitat, and 78.89 % were educated from primary to graduate level.

Majority of patients i.e. 58.89 % were having negative family history, 83.33 % patients were having gradual onset, 94.44 % patients were having relapsing course and 45.56 % were having chronicity of less than 2 years. Cold and moist environment was aggravating factor for all the patients.

Maximum i.e. 85.56 % patients were Vegetarian(As, the diet pattern of Jamnagar people is mainly Veg), 62.22 % patients were having addiction of tea, 80.00 % patients had poor appetite, 84.44 % had mandagni, 47.78 % were krura kostha, 51.11 % were Vata-Kapha Prakriti and 56.67 % were Tamasik Manasik Prakriti. Majority of patients i.e. 95.56% were coming from Anupa Desha and all the patients were more suffered in Varsha & Shita kala.

In majority of patients (94.44%) wrist joint was involved along with Metatarsophalangeal (85.56%), Metacarpophalangeal (82.22%), Ankle (80.00%), Knee

(74.44%), Elbow (24.44%), PIP (20.00%), Shoulder (13.33%), Hip (5.56%), Jaw (5.56%), DIP (3.33%), Lumbo-sacral (3.33%) and Cervical (2.22%) joints were involved. Most of the patients were found to be indulged in Viruddhahara (73.33%), Vishamashana (64.44%), Adhyashana (51.11%), Divaswapna (84.44%), Bhojanottara Vyayama (46.67%), Nishchalatva (37.78%) and Chinta (40.00%).

R.A. factor was found positive in 21.11% patients and negative in 78.89% patients, C-Reactive Protein positive was found in 61.11% patients and negative was found in 38.89% patients, Rheumatoid nodule was present in 34.44% patients and Deformity was observed in 7.78% patients.

According to Pratyatma Lakshana (Cardinal clinical features) all the patients were suffering from Sandhi-shula (Joint pain), Sandhi-shotha (Joint swelling), Sandhi-stabdhatata (Joint-stiffness) and Sandhi-sparshasahyata (Joint tenderness). According to Samanya Lakshana (General clinical features) Alasya and Gaurava were observed in all the patients along with Angamarda, Aruchi, Apaka, Trishna and Jwara were also observed in 98.89%, 97.78%, 44.44%, 36.67% and 26.67% patients respectively.

According to Prabridhdhavastha Lakshana Utsahani, Agni- daurbalya and Vairasya were found in all the patients along with Antrakujana (96.67%), Kukshi shula (95.56%), Bhrama (86.67%), Vid-vibaddhata(75.56%), Anaha (73.33%), Kukshi Kathinata (67.78%), Vairasya (62.22%), Nidra Viparyaya (73.33%), Hridgraham (40%), Jadyata (37.78%), Praseka (15.56%), Bahumutrata (15.56%) and Chhardi(11.11%) were also found.

According to Doshanubandha Lakshana Shula, Stimita and Guru were observed in all the patients as well as Raga, Daha and Kandu were observed in 83.33%, 44.44% and 16.67% patients respectively.

Dosha Dushti wise, Vata and Kapha doshas were more aggravated than pitta dosha in all the patients. Dhatu Dushti wise, Rasa dhatu dushti was found in all the patients along with Asthi, Majja, Mamsa and Rakta dhatu dushti were found in 96.67%, 71.11%, 50% and 11.11% patients respectively. Regarding Sroto Dushti, Rasavaha, Raktavaha, Mamsavaha, Asthivaha and Majjavaha srotas were affected according to previously mentioned respective dhatu dushti, because Dhatu dushti lakshana and Srotodushti lakshan of that Dhatu was same. Again, Annavaha and Purishavaha Sroto dushti were found in all the patients along with Udakavaha and Mutravaha Srotodushti in 36.67% and 18.89% patients respectively.

RESULTS

Effect of the therapy on clinical features & objective parameters in Group A & B (as per Paired 't' test) is shown below :

TABLE NO. 1 : SANDHI SHULA (JOINT PAIN) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	2.20	0.78	64.77	0.50	0.08	18	<0.001
B	40	2.15	1.48	31.39	0.47	0.08	9	<0.001

TABLE NO. 2 : SANDHI SHOTHA (JOINT SWELLING) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	1.93	0.75	61.03	0.38	0.06	19.31	<0.001
B	40	1.43	0.78	45.61	0.48	0.08	8.5	<0.001

TABLE NO. 3 : SANDHI STABDHATA (JOINT STIFFNESS) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	2.23	0.80	66.29	0.50	0.08	18.45	<0.001
B	40	2.18	1.40	35.63	0.42	0.07	11.59	<0.001

TABLE NO. 4 : SANDHI SPARSHA-ASAHYATA (JOINT TENDERNESS) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	2.03	0.75	62.96	0.45	0.07	17.83	<0.001
B	40	1.78	1.13	36.62	0.48	0.08	8.51	<0.001

TABLE NO. 5 : ANGAMARDA (BODY ACHE) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	39	2.0	0.69	65.38	0.47	0.07	17.47	<0.001
B	40	2.0	1.15	42.50	0.36	0.06	14.87	<0.001

TABLE NO. 6 : GAURAVA (HEAVINESS OF THE BODY) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	2.0	0.8	60.0	0.41	0.06	18.73	<0.001
B	40	2.0	1.3	35.0	0.46	0.07	9.54	<0.001

TABLE NO. 7 : ARUCHI (ANOREXIA) :

Group	n	Mean score		% of Relief	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	2.0	0.93	53.75	0.27	0.04	25.49	<0.001
B	38	2.0	1.03	48.68	0.16	0.03	37.0	<0.001

TABLE NO. 8 : WALKING TIME :

Group	n	Mean score		% of Improvement	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	12.65	10.65	15.81	0.23	0.04	55.89	<0.001
B	40	12.18	11.00	9.65	0.55	0.09	13.52	<0.001

TABLE NO. 9 : GRIP STRENGTH :

Group	n	Mean score		% of Improvement	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	88.75	97.75	10.14	5.50	0.87	10.33	<0.001
B	35	94.00	98.17	4.44	2.02	0.34	12.20	<0.001

TABLE NO. 10 : FOOT PRESSURE :

Group	n	Mean score		% of Improvement	S.D.	S.E.	t	p
		B.T.	A.T.					
A	40	19.78	22.60	14.29	0.87	0.14	20.45	<0.001
B	40	21.73	23.55	8.40	0.87	0.14	13.21	<0.001

EFFECT OF THE THERAPY ON CLINICAL FEATURES IN GROUP A & B (AS PER CHI SQUARE TEST)⁵:

TABLE NO. 11 : SANDHI SHULA (JOINT PAIN) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	17	23	40	4.17	<0.05
B	8	32	40		
Column Total	25	55	80		

BT-AT= 2 or more score difference of improvement was placed in Desirable Clinical Improvement (D.C.I)

BT-AT =less than 2 score difference of improvement was placed in Non Desirable Clinical Improvement (N.D.C.I)

TABLE NO. 12 : SANDHI SHOTHA (JOINT SWELLING) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	15	25	40	4.01	<0.05
B	7	33	40		
Column Total	22	58	80		

TABLE NO. 13 : SANDHI SHABDHATA (JOINT STIFFNESS) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	19	21	40	4.38	<0.05
B	10	30	40		
Column Total	29	51	80		

TABLE NO. 14 : SANDHI SPARSHASAHYATA (JOINT TENDERNESS) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	14	26	40	4.27	<0.05
B	6	34	40		
Column Total	20	60	80		

TABLE NO. 15 : ANGAMARDA (BODY ACHE) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	18	22	40	4.53	<0.05
B	9	31	40		
Column Total	27	53	80		

TABLE NO. 16 : GAURAVA (HEAVINESS OF THE BODY) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	19	21	40	4.38	<0.05
B	10	30	40		
Column Total	29	51	80		

TABLE NO. 17 : ARUCHI (ANOREXIA) :

Group	D.C.I	N.D.C.I	Row Total	χ^2	p
A	18	22	40	4.53	< 0.05
B	9	31	40		
Column Total	27	53	80		

EFFECT OF THE THERAPY ON OBJECTIVE PARAMETERS, HB% & ESR-VALUE IN GROUP A & B (AS PER UNPAIRED 't' TEST)⁵:

TABLE NO. 18 : WALKING TIME :

Group-A		Group-B		S.D.	S.E.	t	p
n ₁	χ_1	n ₂	χ_2				
40	2.0	40	1.18	1.08	0.09	8.7	<0.001

TABLE NO. 19 : GRIP STRENGTH :

Group-A		Group-B		S.D.	S.E.	t	p
n ₁	χ_1	n ₂	χ_2				
40	9.0	35	4.17	2.04	0.36	13.30	<0.001

TABLE NO. 20 : FOOT PRESSURE :

Group-A		Group-B		S.D.	S.E.	t	p
n ₁	χ_1	n ₂	χ_2				
40	2.83	40	1.83	1.35	0.19	5.12	<0.001

TABLE NO. 21 : HAEMOGLOBIN PERCENTAGE (HB%) :

Group-A		Group-B		S.D.	S.E.	t	p
n ₁	χ_1	n ₂	χ_2				
40	0.33	40	0.15	0.38	0.08	2.24	<0.05

TABLE NO. 22 : ESR VALUE :

Group-A		Group-B		S.D.	S.E.	t	p
n ₁	χ_1	n ₂	χ_2				
40	6.13	40	2.85	1.69	1.55	2.12	<0.05

TABLE NO. 23 : OVER ALL EFFECT OF THE THERAPY :

Effects	Group A		Group B	
	No. of Patients	Percentage (%)	No. of Patients	Percentage (%)
Complete Remission	00	00	00	00
Major Improvement	26	65	16	40
Minor Improvement	12	30	20	50
No-Improvement	02	5	04	15

DISCUSSION

As per Paired 't' test, both in Group-A & B, all the results were statistically highly significant ($p < 0.001$) on the above mentioned all the clinical features & objective parameters.

As per Chi square test, the results were statistically significant ($p < 0.05$) on the Clinical features like Sandhishula, Sandhishotha, Sandhi Stabdhatta, Sandhi Sparshasahyata, Angamarda, Gaurava, Aruchi. It means that the treatment of group-A showed statistically

significant effect on these clinical features in comparison to the treatment of group-B.

As per Unpaired 't' test, the results were statistically highly significant ($p < 0.001$) on the Objective parameters viz. Walking time, Grip strength, Foot pressure and the results were also statistically significant ($p < 0.05$) on Hb % and ESR value. It reveals that group-A treatment was more effective than group-B treatment in respect of these Objective parameters, Hb % and ESR value.

Over all Effect of the Therapy express that maximum patients i.e. 65 % in Group-A showed major improvement, while in Group-B maximum patients i.e. 50 % showed minor improvement.

Probable Mode of Action of the drugs: The ingredients of the Alambushadi Churna tablet and Simhanada Guggulu both were containing Katu-Tikta rasa, Ushna, Laghu, Ruksha, Tikshna guna, Ushna virya, Katu or Madhur vipaka and Vata-Kapha-shamaka properties and had Deepan, Amapachan, Shothaghna, Vedanasthapaka, Jwaraghna, Rasayana, Balya, Mutrala and Amavatahara etc. actions which helped to enhance the agni, to mitigate the Ama, to reduce the clinical manifestations of Amavata and to break down the samprapti of Amavata.

The ingredients of the Shatapushpadi Lepa were containing Ushna, Laghu, Ruksha, Tikshna guna, Ushna virya and Vata-Kapha-shamaka properties and had also Shothahara and Vedanasthapak actions. Hence, Shatapushpadi Lepa when used locally with warm water, it helped to reduce the local pain, swelling, tenderness and stiffness of the affected joints and to break down the Samprapti of the disease Amavata, when it was used locally over affected joints.

CONCLUSION

Lastly it can be concluded that Amavata looks similar to Rheumatoid arthritis in its clinical appearance and Group-A therapy is more effective than Group-B therapy in the treatment of Amavata. It was happened due to combined effect of Alambushadi Churna tablet, Simhanada Guggulu and Shatapushpadi Lepa in Group-A therapy as compared to the combined effect of Simhanada Guggulu and Shatapushpadi Lepa in Group-B therapy.

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हिन्दी सारांश

आमवात की चिकित्सा में अलंबुशादि चूर्ण वटी एवं सिंहनाद गुग्गुलु के प्रभाव का अध्ययन

सरोज कुमार देबनाथ एवं सुधाबेन एन. व्यास

प्रस्तुत अध्ययन में कुल ९० आमवात के रूग्णों को पंजीकृत करके दो समूहों में बाँटा गया। एक समूह में अलंबुशादि चूर्ण की ४ वटी दिन में तीन बार दूध के साथ एवं सिंहनाद गुग्गुलु १ ग्राम दिन में तीन बार गरम जल के साथ ४५ दिनों तक दी गयी और शतपुष्पादि लेप संधिप्रदेश में लगाने के लिए दिया गया। दूसरे समूह में केवल सिंहनाद गुग्गुलु मुख मार्ग द्वारा और शतपुष्पादि स्थानिक लेप दिया गया। प्रथम समूह में चिकित्सा द्वारा ६५ प्रतिशत रूग्णों को उत्तम लाभ प्राप्त हुआ।

