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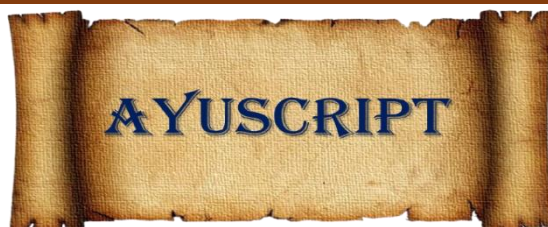
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A Randomized Controlled Trial to Compare Efficacy of Amavata Pramathini Vati with Simhanad Guggulu When Given with Vaitaran Basti in the Management of Amavata

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ABSTRACT:

Amavata is a particular type of disease that is mentioned in Ayurveda since the period of Madhavkar, under the category of Vata-Kaphaja disorder. The term Ama ordinarily means, unripe, uncooked, immature undigested substance. It is produced from the impaired function of the *kayangni*. It is a toxic substance of gastroenteric origin. Vata is the chief functional operator of the all types of voluntary or involuntary movements of body. Vitiated Vata Dosha along with Ama is termed as Amavata. It indicates the propulsion of Ama by vitiating Vata throughout the body getting lodged in Sandhithana (joint areas) producing Amavata. Amavata is such a disease of chronic joint pain and body ache, accompanied by swelling of some or all of the Synovial joints. Angamarda, Aruchi, Trishna, Alasya, Gourava, Klama, Apaka and Fever. Amavata can be correlated with Rheumatoid Arthritis. In Amavata Vata as a Dosha and Ama are chief pathogenic factors. They are exactly opposite in the properties so difficult to treat. It is the disease of Madhyam margag roga and having Chirkari Swabhava, sometimes it can also be manifested as the acute case. Chakradatta was first to describe in the treatment for Amavata. He gave Basti chikitsa especially Vaitaran Basti is considered as the chief treatment regimen for Amavata. Amavata Pramathini Vati is one of the formulations which is prescribed to treat Amavata. The description of Amavata Pramathini Vati is found in Bhaishajya Ratnavali. Amavata Pramathini Vati is a formulation of five drugs *Kalmishora*, *Arkamula*, *Shuddha Gandhaka*, *Lohabhasma* and *Abhrakbhasma*. These drugs play a significant role in reducing the symptoms and to treat the Amavata. The drugs have VataKaphaghna property which reduce Vata and Kapha Doshas from the body and reduce the symptoms of Amavata.

Key words: Amavata, Rheumatoid Arthritis, Amavata Pramathini Vati, Vaitaran Basti, Simhanad Guggul.

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Introduction:

Ayurveda is an ancient science. Ayurveda is not only about treating disease but also preventing its occurrence. So many Ayurvedic medicines has been described in the Ayurvedic classical books for the treatment of Amavata. Amavata is a most common problem in the society in modern era¹. According to Ayurveda, proper diet and its digestion is considered as one of the basic pillars of life. Ability to digest and metabolise the different type of food determines the state of our health. Agni [digestive power] has the important role to play in digestion of food and various toxins that we ingest along with food. Ayu (long life), Varna (complexion), Bala (strength), Ojas (immunity) etc. All are under influence of Agni². The basic role of Agni in body is to disintegrate the food into simplest possible components to make it easy for assimilation. This occurs at the level of GIT and the cellular level. Due to Dhatwagnimandya and Bhutagnimandya, there is production and accumulation of Ama³. Amavata is such a disease of chronic joint pain and body ache, accompanied by swelling of some or all of the Synovial joints. Angamarda, Aruchi, Trishna, Alasya, Gourava, Klama, Apaka and Fever. In the later stage pain may begin to migrate from place to place with a Vrishchika Danshavat vedana and burning sensation⁴. Amavata is particular type of disease that is mentioned in Ayurveda since the period of Madhavakar, under the category of Vata-Kaphaja disorder. In Amavata Vata as a Dosha and Ama are chief pathogenic factor. They are exactly opposite in the properties so difficult to treat. It is the disease of Madhyam margag roga and having Chirkari Swabhava, sometimes it can also be manifested as the acute case⁵. Amavata can be correlated with Rheumatoid Arthritis. The sign and symptoms of both diseases are very similar⁶. Rheumatoid Arthritis clinically presents as polyarthritis involving small and large diarthrodial joints of the extremities usually in a symmetrical pattern⁷. The prevalence of RA is 0.5-1% in

Indian population; Women affected three times more than men. The prevalence of RA increases between 25-55 yrs of age, after which it plateaus until the age of 75 and then decreases⁸. In Amavata mainly joints of Hasta (hand), Pada (foot), shira (head and neck), Gulpha (ankle) are affected. Initially Amavata starts from small joints of hands and spread. The current available medical interventions cannot satisfy the objectives of an ideal therapy. The available pain relieving agents are associated with substantial risk of gastrointestinal ulceration and bleeding. So safety and efficacy of treatment is the need of hour. Hence present study is taken to compare the efficacy of Amavata Pramathini Vati with simhanad Guggulu when given with vaitaran basti in the Amavata patients.

Aims And Objectives-

To study the efficacy of Amavata Pramathini Vati with Simhanad Guggul when given with Vaitaran Basti

Materials And Methodology-

Sampling Method - Patients of Amavata attending OPD will be screened for the study. Eligible and willing patients will be enrolled in the study.

Method of Selection of Patient

Group A- 30 patients were included in Group A and administered Vaitaran Basti + Amavata Pramathini Vati.

Group B - 30 patients were included in Group B and administered Vaitaran Basti + Simhanad Guggul

CRITERIA OF ASSESSMENT OF SUBJECTS⁹-

1. Joint Score
2. Stambhata (Morning Stiffness)
3. Sandhishula (Joint Pain)
4. Sandhishotha (Swelling of joint)
5. Angamarda (Body Pain)
6. Alasya (Laziness)

Objective Criteria-***ESR****Materials Used-**

In the present study following drugs were utilized.

VAITARANA BASTI¹⁰

INGREDIENTS-

*Saindhav Lavana:1 karsha(12g)

*Jaggary(Guda):1 shukti(24g)

*Chincha:1 pala(48gm)

*Gomutra:1 kudava(192ml)

*Tila Taila(50ml)

Initially 24g (1 shukti) of jaggary (Guda) was mixed uniformly with equal quantity of Gomutra.12g(1 karsha) o saindhava was added to the above. Til Taila was added till the mixture becomes homogenous. 48g (1 pala) of chincha kalka was taken and added to above said mixture carefully. Lastly remaining quantity (out of 192ml(1 kudava)) of Gomutra was added slowly and mixing continued so as to have uniform Vasti Dravya.

AMAVATA PRAMATHINI VATI¹¹-**INGREDIENT-**

*Kalmishora

*Arkamula

*Shuddha Gandhaka

*Lohabhasma

*Abhrakbhasma

Method of Preparation-

Kalmishora, Arkamula, Shuddha Gandhaka, Lohabhasma, and Abhrakbhasma are mixed with equal quantity in an iron vessel. Then add Amalatas Patra Swarasa with above mixture to make a pills of 2 ratti.

Simhanad Guggul¹²**Ingredient-**

1) Amalaki

2) Hareetaki

3) Bibhitaki

4) Shuddha Gandhak

5) Shuddha Guggulu

6) Erand tail

Procedure of Preparation- Kashaya of Triphala is prepared in an iron vessel. Erand Taila is added in the kashaya and boiled. When liquid is getting concentrated Gandhaka and Guggul is added and mixed well till it gets the consistence for making pills.

Drug Regimen

GROUP	GROUP A Trial Group	GROUP B Control Group
Drug Name	Tab.Amavata Pramathini Vati	Tab.Simhanad Guggul
Dose	500mg(BD)	500mg(BD)
Route of Administration	Oral	Oral
Duration of treatment	28 Days	28 Days
Follow up	7 th day	7 th day
Number of Patients	30	30
Anupan	Koshnajaal	Koshnajaal

search in Ayurveda

Observation and Result-

Assessment Criteria of Stambhata(Morning Stiffness)-

Sr. No	Symptoms	Grade
1.	No Stiffness	0
2.	For 0-29 min	1
3.	For 30-59 min	2
4.	Above 60 min	3

Assessment of Sandhishula(Joint Pain)-

Sr. No	Symptoms	Grade
1.	No pain	0
2.	Pain at the beginning of physical activity	1
3.	Pain permanently present during physical activity	2
4.	Pain present even at rest	3

Assessment of Sandhishotha(Joint Swelling)

Sr. No	Symptoms	Grade
1.	Absent	0
2.	2mm-4mm, slight pitting, disappears rapidly	1
3.	4mm-6mm, pit is noticeably deep, may last more than 1 min	2
4.	6mm-8mm, pit is very deep, last for 2-5 min	3

Angamarda (Body Pain)-

Sr. No	Symptoms	Grade
1.	Absent	0
2.	Superficial to deep muscle pain	1
3.	Muscle with Bony pains	2
4.	Severe body pain	3

Effect of therapy according to % Relief in Patients

Table shows relieved score and % Relief in Patients of both groups

Pt. No.	Group A				Pt. No.	Group B			
	B.T.	A.T.	Relief	%Relief		B.T.	A.T.	Relief	%Relief
1	29	9	20	68.96	1	27	11	16	59.26
2	26	12	14	53.84	2	25	11	14	56
3	27	7	20	74.07	3	28	15	13	46.43
4	28	7	21	75	4	23	7	16	69.57
5	28	2	26	92.86	5	26	11	15	57.69
6	23	9	14	60.87	6	24	14	10	41.67
7	26	8	18	69.23	7	26	10	16	61.54
8	25	11	14	56	8	23	12	11	47.83
9	28	11	17	60.71	9	28	9	19	67.86
10	21	8	13	61.90	10	21	8	13	61.90
11	27	14	13	48.15	11	26	16	10	38.46
12	24	8	16	66.67	12	25	11	14	56
13	22	6	16	72.73	13	23	9	14	60.87
14	19	4	15	78.95	14	27	8	19	70.37
15	18	7	11	61.11	15	28	15	13	46.43
16	21	7	14	66.67	16	24	9	15	62.5
17	26	9	17	65.38	17	28	12	16	57.14
18	18	6	12	66.67	18	24	14	10	41.67
19	23	8	15	65.21	19	23	7	16	69.57
20	22	9	13	59.09	20	28	17	11	39.29
21	28	12	16	57.14	21	28	8	20	71.43
22	23	6	17	73.91	22	26	10	16	61.54
23	24	5	19	79.17	23	26	12	14	53.85
24	22	10	12	54.55	24	25	15	10	40
25	24	9	15	62.5	25	26	9	17	65.38
26	26	9	17	65.38	26	21	6	15	71.43
27	21	8	13	61.90	27	22	11	11	50
28	26	10	16	61.54	28	27	14	13	48.15
29	27	10	17	62.96	29	24	10	14	58.33
30	23	9	14	60.87	30	23	7	16	69.57
Average Relief				65.47%	Average Relief				56.72%

shows Average % Relief in Patients and in Symptoms

Sr. No.	Group	Avg. % Relief (Patients)	Avg. % Relief (Symptoms)
1	Group A	65.47%	64.70%
2	Group B	56.72%	56.73%

Discussion:

The present study type was Randomized Controlled Study. It was entitled as "A Randomized Controlled Trial to Compare Efficacy of Amavata Pramathini Vati With Simhanad Guggulu When Given With Vaitaran Basti In The Management of Amavata". Discussion and critical analysis are as follow.

Discussion on Selection of Topic- The incidence of patient suffering from Amavata is very common in India. Due to wide spectrum of disease, much prevalence in the society and lack of effective

medicine, the disease is being chosen for the study. It is one of the major and chronic diseases which the world is facing. It is a chronic, systemic inflammatory polyarthrititis that primarily affects small diarthrodial joints of hands and feet's in systemic pattern. The current available medical interventions cannot satisfy the objectives of an ideal therapy. The available pain relieving agents are associated with substantial risk of gastrointestinal ulceration and bleeding. So safety and efficacy of treatment is the need of hour. Amavata Pramathini Vati is a unique

Kharaliya Rasayana mentioned in Bhaishajyaratnavali for the management of Amavata. The main ingredients are Kalmishora, Arkamula, Shuddha Gandhak, Abhraka Bhasma, Loha Bhasma, etc. The contents of Amavata Pramathini Vati are easily available and cost effective.

Discussion on Methodology-

Trial Group (Group A) and Control Group (Group B) comprised 30 patients each of Amavata. Patients of Trial group were treated with Vaitaran Basti and Amavata Pramathini Vati while Patients of Control group were treated with Vaitaran Basti and Simhanad Guggul.

% Relief in Patients-

In Group A, 04 patients have shown Marked improvement, 25 patients have shown Moderate improvement and 1 patient have shown Mild improvement. In Group B, 21 patients have shown Moderate improvement, 09 patients have shown Mild improvement. Average % Relief in Patients of Group A is 65.47% and Average % Relief in Patients of Group B is 56.72.

% Relief in Symptoms-In Group A, 11 symptoms have shown Moderate improvement. In Group B, 10 symptoms have shown Moderate improvement and 1 symptom has shown Mild improvement. Average % Relief in Symptoms of Group A is 64.70% and Average % Relief in Symptoms of Group B is 56.73.

Effect of Therapy according Average % Relief- Group A has shown better effect than Group B to reduce score in Patients and in Symptoms (Table 5.29). Hence according to % Relief Amavata Pramathini Vati with Vaitaran Basti is effective than Simhanad Guggul in Amavata to reduce score in Patients and in Symptoms.

Conclusion:

After literary study, clinical trials, data collection, data classification, data presentation and data analysis in the dissertation work "A Randomized Controlled Trial to compare efficacy of Amavata Pramathini Vati with Simhanad Guggulu when given Vaitaran Basti in the management of Amavata" here is time to

conclude few interferences found from the study.

1. Amavata is one of the major diseases causing disability.

2. Amavata in present study was found mostly prevalent in 35 to 40 years age group.

3. Housewife, Farming & Labour, Manda Agni, Mixed diet, vata-kapha and kapha vata prakruti, were found most incident in Amavata.

4. Amavata Pramathini Vati with Vaitaran Basti reduced all Angamarda, Aruchi, Trushna, Alasya, Joint Involvement Score, Gaurava, Apaka, Sandhishotha, Shoola, Stambha and ESR significantly. (Wilcoxon Signed Ranks test; $P < 0.05$), except Angamarda, Joint Involvement, Gaurava in Amavata. (Mann-Whitney's U test; $P < 0.05$)

5. Simhanad Guggul with Vaitaran Basti reduced all Angamarda, Aruchi, Trushna, Alasya, Joint Involvement Score, Gaurava, Apaka, Sandhishotha, Shoola, Stambha and ESR significantly. (Wilcoxon Signed Ranks test; $P < 0.05$), except Angamarda, Joint Involvement, Gaurava in Amavata. (Mann-Whitney's U test; $P < 0.05$)

6. When compared Amavata Pramathini Vati and Simhanad Guggul both were found almost equally effective for all factors (Mann Whitney's U test; $P > 0.05$), except Angamarda, Joint Involvement, Gaurava in Amavata. (Mann-Whitney's U test; $P < 0.05$)

7. In Trial Group (Vaitaran Basti+ Amavata Pramathini Vati) Average % Relief was 65.47% and In Control Group (Vaitaran Basti+ Simhanad Guggul) Average % Relief was 56.72.

8. Amavata Pramathini Vati is effective, safe, and easy to consume to treat Amavata.

9. No complications or adverse drug effects were observed during the study with both of the drugs.

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