CLINICAL EVALUATION OF DHATRI BHALLATAKA VATI   IN AMAVATA

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ABSTRACT

Amavata is described as a disease in Madhava Nidana by Madhavakara in Ayurveda. Amavata is one the most common joint disorders. In modern era, dietary habits, lifestyle and environment have led to various autoimmune disorders, Amavata is one among them. Amavata has pain in joints with swelling as cardinal feature. Amavata can be correlated with Rheumatoid arthritis in view of its clinical features. In conventional medical science, NSAIDS and some DMARDS drugs are used for its management, but they cause certain side effects in the patients. Ayurveda provides an excellent therapy for it. The present clinical trial was conducted with the same objective to provide a safe and effective therapy to the patients of Amavata. The present study was conducted in 30 patients having classical symptoms of Amavata (Sandhi shoola, Sandhi shotha, Sandhi Graha, Sparsha Asahatwa, Morning stiffness). Dhatri Bhallataka Vati has been selected from the text Rasatantra sara va siddha prayoga sangraha. It consists of nine ingredients- Shuddha Bhallataka, Amalaki, Haritaki, Vibhitaki, Maricha, Pippali, Shunti, Krishna Tila and Guda. The patients were given Dhatri Bhallataka Vati for 45 days. Patients with any other acute or chronic systemic illness or infection were excluded from the study. By applying the "t" test,observations and results obtained were analyzed statistically. The drug has shown its beneficial effects in the patients of Amavata due to its Vatashamaka, Agnideepana, Amapachana, and Rasayana effects in the body. A significant decrease in the erythrocyte sedimentation rate and c-reactive protein in all the patients was also noticed. All the results obtained were highly significant statistically. Thus, it can be implicated that the Dhatri Bhallataka vati has beneficial effects in the patients of Amavata.

Key words: Amavata , Rasayana , Rheumatoid arthritis, Dhatri Bhallataka vati

INTRODUCTION

Amavata is first mentioned as a separate disease in Madhav Nidana, where it is stated that mandagni plays a key role in the manifestation of the disease[1].This theory is very well supported by the view of Acharya Vagbhatta that the main cause of all diseases is Mandagni[2]. The name Amavata is because of its two major samprapti ghataka (pathogenic constituents) viz. Ama and Vata. Madhavakar mentioned that Amavata is a disease where Ama and Vata both play a crucial role in the samprapti [3]. Consumption of viruddha ahara[4] by the person having mandagani is the main causative factor for formation of Ama . Ama and Vata are main key elements but Kapha anubandha or Pitta anubandha is also involved in samprapti [5]. Vitiation of the Kapha dosha mainly Shleshak kapha along with Ama is seen in the Amavata. It can be correlated with Rheumatoid Arthritis in which joint pain and swelling with tenderness is the clinical presentation.Acharya Madhava has described the most characteristic feature of this disease: severe pain similar to a scorpion bite. Asthi and Sandhi are the chief sites of presentation of the cardinal symptoms such as Sandhishoola, Sandhigraha, Sandhi Shotha, etc. These symptoms resemble the cardinal features of rheumatoid arthritis, i.e. pain, swelling, stiffness, fever, general debility, etc. Rheumatoid arthritis is a chronic immuno-inflammatory systemic disease that affects mainly the synovial joints, with a possibility of extraarticular manifestations[6] . In the management of Amavata sequential employment of Dipana, Amapachana, Shodhana, and Shamana therapies have been mentioned[7] . Dhatri Bhallataka vati which has been mentioned in Rasatantrasara va siddha prayogasangraha, Prathama Khanda, Gutika Prakarana[8] has been selected for the present study to evaluate its efficacy in Amavata.

Aim and Objectives:

The present clinical study has been planned to evaluate the therapeutic efficacy of Dhatri Bhallathaka Vati[9] in Amavata.

Materials and Methods:

- The patients having classical symptomatology of Amavata have been selected from OPD of TTD's S.V. Ayurvedic Hospital, Tirupati, irrespective of Sex, Religion, and Occupation etc.
- A special detailed clinical proforma has been prepared to incorporate selected symptoms and signs based on Ayurvedic Classics. A detailed history has been taken and a complete physical examination has been carried out.
- Total 36 patients with signs and symptoms of Amavata were registered. Out of them 30 patients completed the course of treatment

Criteria for Inclusion of Patient:

- Patients aged between 16-60 years were selected irrespective of Sex, Religion, Occupation etc.
- Patients with symptoms of Amavata as per Ayurvedic classics were selected. i.e Sandhi shoola, Sandhi shotha, Sandhi Graha, Sparsha Asahatwa, Morning stiffness

Criteria for Exclusion of Patient:

- Patients of age less than 16 years and more than 60 years.
- Patients with other systemic complications like Cardiovascular, Nephropathic , Neuropathic etc.
- Patients with any type of Carcinoma.

Posology:

- **Internal Therapy :**   Dhatri Bhallataka Vati

- **Dose**   :   125mg

- *Kala*   :   Twice a day after meals

- *Anupana*   :   Jala

- **Duration**   :   45days

- **Follow up**   :   on every 15th days

Diagnostic criteria:

1) Subjective : Clinical signs and symptoms of Amavata

2) **Objective**   : ESR and R.A factor

- Patients were examined clinically and details regarding disease starting from history taking, physical examination, signs and symptoms as Sandhi shoola, Sandhi shota, Sandhi graha, Sparsha asahatwa, Morning stiffness were recorded in a specially prepared clinical proforma. This was prepared, based on Inclusive criteria.

- Informed consent of all the registered subjects was taken before starting the interventions. The patients were assessed clinically before and after treatment.

Criteria for Assessments :

General observation:

Various demographic parameters viz. Age, Marital Status, Religion, Nature of work etc. along with specific features of *Prakriti, Satva, Samhanana* etc. were analyzed in the present clinical trial.

Assessment:

Criteria of assessment were kept based on relief in the sign and symptoms of *Amavata* before and after the treatment. For this purpose, cardinal signs and symptoms were given scores.

1. *Sandhi Shoola*	Grade
No Complaint	0
Mild: Pain in joints only on movement	1
Moderate: Frequent pain without movement, but bearable	2
Severe: Pain persistent and unbearable	3

2. *SandhiShotha*	Grade
No complaints	0
Mild: Slight obvious	1
Moderate: Covers well the bony prominences	2
Severe: Much elevated	3

3.*Sandhigraha*	Grade
No Stiffness	0
Mild: Stiffness for 5minutes to 1hour	1
Moderate: Stiffness for 1-2 hours	2
Severe: Stiffness for more than 2 hours	3

4. Morning Stiffness	Grade
No Stiffness	0
Mild: Early morning stiffness< 30minutes	1
Moderate: Early morning Stiffness >30minutes and < 45minutes	2
Severe: Morning Stiffness > 45minutes	3

5.*Sparshaasahatwa*	Grade
No Tenderness	0
Mild: Tenderness but bearable	1
Moderate: Tender and winced	2
Severe: Wincing of face and withdrawal of affected part	3

Criteria for Overall Effect of Therapy

The total effect of the therapy was assessed considering the following criteria.

Assessment on basis of percentage of relief obtained by the therapy:

S. No.	Effect	Percentage of relief
1.	Marked Improvement	76% - 100%
2.	Moderate Improvement	51% - 75%
3.	Mild Improvement	26% - 50%
4.	No improvement	< 25%

Statistical evaluation of results

The obtained information was analysed statistically in terms of mean score (x), Standard Deviation (S.D.), Standard Error (S.E), Paired t-Test was carried out at the level of 0.05, 0.01, and 0.001 of P levels. For the more effectiveness of therapy paired t-Test is carried out. The results were interpreted as

- Insignificant   : $p > 0.05$
- Significant   : $p < 0.05$
- Highly significant   : $p < 0.01$, $p < 0.001$
- Extremely significant   : $p < 0.0001$.

OBSERVATIONS :

Total 36 patients were registered among them 30 patients had completed the treatment and 6 patients were dropped out from the course of treatment due to various reasons.

Out of 30, maximum number of patients i.e. 16 (53.33%) were between 36-45 years age group. Maximum number of patients i.e. 21 (70.00%) were female and 09 patients (30.00%) were male. Maximum number of patients i.e. 24 (80%) were Hindus, 04 patients (13.33%) were Muslims, 02 patients (6.66%) were Christians. Majority of the patients i.e. 24 (80%) were married and 6 patients (20%) were unmarried. Maximum number of patients i.e. 21 (70.00%) were from Urban area, while 09 patients (30.00%) were from Rural area. Maximum number of patients i.e. 18(60%) were housewives, 4 patients (13.33%) were engaged with sedentary work and 6 patients (26.66%) were labour workers. Maximum number of patients i.e. 26 (86.66%) were consuming mixed diet and 4 patients (13.33%) were taking vegetarian diet only. Maximum number of patients i.e.19 (63.33%) were having Mandagni, 5 patients (16.66%) were having Vishamagni and 6 patients (20%) were having Samagni. Maximum number of patients i.e 18 (60%) had disturbed sleep and 12 patients (40%) had normal sleep. Maximum number of patients i.e. 19 (63.33%) were of Vata- Kapha prakruti, 6 patients (20%) were of Vata-Pitta prakruti, 5 patients (16.6%) were of Pitta-Kapha prakruti. Maximum number of patients i.e. 11(36.66%) patients had chronicity of 3 to 4 years, 7patients (23.33%) had chronicity of 1 to 2 years, 5 patients (16.66%) had chronicity less than 1 year, 4 patients (13.3%) had chronicity of 4 to 5 years and 3patients (10%) had chronicity more than 5years. Sandhi shoola (Pain in joint), was observed in all patients i.e 100% followed by Sandhi graha(Stiffness) and Morning stiffness observed in 27 patients i.e 90%, Sandhi sotha(Swelling) in 21 patients (70%) and Sparsa asahatwa (Tenderness) in 18 patients (60%). 25 patients (83.33%) had abnormal ESR values and 22 patients (73.33%) had abnormal RA factor values.

EFFECT OF THERAPY:

Study was carried out in 30 patients. To find relief in patient and in turn effect of therapy before and after symptom scores were assessed. Overall effect was calculated in the form of percentage in all 30 patients.

Table No 01 : showing the Showing effect of *Dhatri Bhallataka Vati* on Subjective parameters in 30 patients:

Parameters	n	Mean		Mean Difference	Relief %	SD		SE		t Value	p Value
		B.T	A.T			B.T	A.T	B.T	A.T		
SandhiShoola	30	2.56	0.90	1.66	64.93	0.57	0.55	0.10	0.10	19.03	<0.0001
SandhiSotha	21	2.33	0.76	1.57	67.34	0.93	0.63	0.17	0.11	7.50	<0.0001
Sandhigraha	27	1.70	0.40	1.30	76.08	0.73	0.61	0.13	0.11	12.04	<0.0001
Sparshaasahatwa	18	2.55	0.77	1.78	69.56	0.68	0.63	0.12	0.11	10.01	<0.0001
Morning Stiffness	27	1.48	0.37	1.11	75	1.06	0.61	0.19	0.11	7.37	<0.0001

Dhatri Bhallataka Vati showed statistically Extremely significant relief (P<0.0001) in Sandhi shoola, Sandhi shotha, Sandhi graha, Sparsha asahtwa and Morning stiffness.

Table No 02 : Showing Effect of Dhatri Bhallataka Vati on objective parameters in 30 patients

Parameters	n-	Mean		Mean difference	% Relief	S.D		S.E		t value	p value
		B.T	A.T			BT	AT	BT	AT		
ESR	25	2.44	0.64	1.80	73.77	1.07	0.57	0.19	0.10	9.12	<0.0001
RA Factor	22	1	0.18	0.82	81.81	0.45	0.35	0.08	0.06	6.59	<0.0001

In the present study *Dhatri Bhallataka Vati* showed Statistically Extremely significant improvement (P<0.0001) in ESR and RA Factor.

Overall assessment of clinical trial:

Result	Number of Patients	% Patients
Marked Improvement	16	53.33%
Moderate Improvement	9	30.00%
Mild Improvement	4	13.33%
No improvement	1	3.3%

Among 30 patients, 16 patients (53.33%) had marked improvement, 9 patients (30%) had moderate improvement, 4 patients (13.33%) had mild improvement and 1 patient (3.3%) had no improvement.

From this observation, it is clear that the patients who are treated with Dhatri Bhallataka Vati have shown favourable response in regards to the clinical parameters, hematological investigations of Amavata.

Discussion :

The causative factors of Amavata i.e viruddha ahara & chesta, nischalatva, (sedentary life style) and doing vyayama (excerise) after taking guru and snigdha (oily) food leads to the decreased secretion of gastric juices ultimately responsible for indigestion (gourava, aruchi, trishna etc.). If one is exposed to nidana, then it leads to formation of ama which further leads to the vitiation of dosha. This ama circulates in the body, propelled by the vitiated vata exhibiting an affinity to get lodged in the shleshmasthana i.e sandhi. Further this ama undergoes more and more vitiation in that sleshma sthana and mixes with tridosha and circulates through different srotas causing obstruction to that srotas. Ama produces weakness of the body and heaviness in chest region. Further this vitiated ama and vata will lodge in trika sandhi leading to the symptoms like gatra sthabdhata, sandhi shula, sandhi shotha[10].

Dhatri Bhallataka Vati contains Shuddha Bhallataka (Semecarpus anacardium), Amalaki (Phyllanthusemblica), Haritaki (Terminalia chebula) Vibhitaki (Terminalia bellarica), Maricha (piper nigrum), Pippali (Piper longum), Shunti (Zingiber officinale), Krishna Tila (Sesamum indicum Linn), Guda[11].

All these dravya mainly possess Katu, Tikta rasa, Ushna veerya, Laghu, Tikshna guna, Katu vipaka, Vatakapha hara, Deepana, Pachana, Shoolahara, Sothahara and Sroto shodhana properties, which may show significant effect on Amavata

EFFECT ON SUBJECTIVE PARAMETERS:

Effect on Sandhi shoola:

All the 30 patients were having Sandhi shoola with the mean initial score of 2.56 which was reduced to 0.90 after the treatment. The improvement is statistically extremely significant ($P<0.0001$). Sandhi shoola is mainly due to ama and tridosha. The extremely significant relief in Sandhi shoola may be due to Vedana sthapana property of Bhallataka and Maricha, Ushna veerya of all the ingredients pacify vata & kaphadosha, Snigdha guna of Bhallataka, Shunti, Tila and Pippali pacify vatadosha, Madhura vipaka of Bhallataka, Amalaki, Haritaki,,Vibhitaki,Shunti and Guda pacifies vata& pittadosha.Deepana, pachana properties of Bhallataka, Pippali, Maricha and Shunti help in Amapachana. Madhura rasa of Guda pacifies vata.

Effect on Sandhi sotha:

Among 30 patients, 21 patients were having Sandhi shotha with the mean initial score of 2.33 which was reduced to 0.76 after the treatment. Statistically this improvement is extremely significant ($P<0.0001$). Sandhi sotha is mainly due to Ama and tridosha vitiated by that Ama. Sotha hara and Sweda janaka properties of Bhallataka pacify Sandhi sotha by clearing the Ama and Srotas. Ushna veerya of Bhallataka, Haritaki, Vibhitaki, Shunti, Pippali, Maricha and Tila pacify vata and kapha dosha. Deepana, Pachana properties of Bhallataka, Pippali, Maricha helps inAmapachana.

Effect on Sandhi graha:

Among 30 patients, 27 patients were having Sandhi graha with the mean initial score of 1.70 which was reduced to 0.40 after the treatment. This improvement is statistically extremely significant (P<0.0001). Sandhi graha is mainly due to vata dosha and ama. Sweda janaka property of Bhallataka helps in relieving joint stiffness. Ushna veerya of Bhallataka, Haritaki, Vibhitaki, Shunti, Pippali, Maricha, Tila and Guda pacify vata dosha. Deepana, Pachana properties of Bhallataka, Pippali, Maricha helps in Amapachana.

Effect on Sparsha asahatwa:

Among 30 patients, 18patients were having Sparsha asahatwa with the mean initial score of 2.55 which was reduced to 0.77 after the treatment. Statistically this improvement is extremely significant (P<0.0001). Sparsha asahatwa is mainly due to pitta. The extremely significant relief in Sparsha asahatwa may be due to Sroto vishodhana and Ama pachana due to Dhatri Bhallataka Vati

Effect on Objective parameters:

Among 30 patients, 25 patients were having abnormal ESR values with the mean initial score of 2.44 which was reduced to 0.64 after the treatment. Statistically this improvement is extremely significant (P<0.0001).

Among 30 patients, 22 patients were having abnormal RA factor values with the mean initial score of 1.00 which was reduced to 0.18 after the treatment. Statistically this improvement is extremely significant (P<0.0001).

The extreme significant relief in objective parameters may be due to Ama pachana, Sroto mukha vishodhana by Dhatri Bhallataka vati.

Probable mode of action of drug:

Acharya Charaka has mentioned that the drugs show their actions due to their five properties viz. Rasa, Guna, Virya, Vipaka and Prabhava. Action of a compound formulation is decided by the action of major ingredient or by synergistic action of all the ingredients. The actions of ingredients of Dhatri Bhallataka Vati are as follows:

Ingredients	*Rasa*	*Guna*	*virya*	*Vipaka*	*Karma*	Biological Action
Bhallataka[21]	*Katu Tikta Kashaya*	*Laghu Tikta Snigdha*	*Ushna*	*Madhura*	*Kapha-vatahara Rasayana Vrshya Dipana Pachana*	Anti-inflammatory Antioxidant Hypoglycemic Anticarcinogenic[12]
Amalaki[22]	*Madhura Amla Katu Tikta Kashaya*	*Ruksha Laghu*	*Sheeta*	*Madhura*	*Tridoshahara Rasayana Vrishya*	Analgesic Gastro protective Anti-inflammatory Immunomodulatory[13]
Haritaki[23]	*Madhura Katu Tikata Kashaya*	*Ruksha Laghu*	*Ushna*	*Madhura*	*Tridoshahara Vata anulomana Rasayana Lekhana*	Anti inflammatory Anti fungal Rejuvenating Laxative[15]
Vibhitaki[24]	*Kashaya*	*Ruksha Laghu*	*Ushna*	*Madhura*	*Kapha-pitta hara Bhedana*	Analgesic Antioxidant Immune-modulatory[14]
Pippali[25]	*Katu*	*Laghu Snigdha Tikshna*	*Ushna*	*Madhura*	*Kapha-vata hara Dipana Vrshya Rasayana*	Anti inflammatory Immunomodulator Hypoglycaemic[16]
Maricha[26]	*Katu*	*Laghu Ruksha Tikshna*	*Ushna*	*Katu*	*Kapha-vata hara Dipana Pachana*	Anticonvulsant Anti inflammatory Muscle ralaxant[17]
Shunti[27]	*Katu*	*Laghu Snigdha*	*Ushna*	*Madhura*	*Vata-kapha hara Dipana Bhedana*	Antiinflammatory Antioxidative Antimicrobial[18]
Tila[28]	*Katu*	*Laghu*	*Ushna*	*katu*	*Vatahara Agni depana Balya*	Cardioprotective Antidiabetic Immunity booster[19]
Guda	*Madhura*	*Na-atisheeta Snigdha*	*Ushna*	*Madhura*	*Vata-Pitta shamaka Kapha vardhaka*	Immunity booster Regulates bood pressure Increases hemoglobin[20]

Probable Rasa Panchaka of Dhatri Bhallataka Vati

Rasa   :   Katu , Tikta

Guna   :   Laghu, Tikshna, Ruksha

Virya   :   Ushna

Vipaka   :   Madhura

Karma   :   Vata-Kapha Shamaka, Dipana, Amapachaka, Shulangna,

             Shotha hara

Properties of Dhathri Bhallataka Vati:

Katu rasa is Chedaka, Marga vivaraka and Kaphashamaka. Tikta rasa is vishaghna, lekhana, amapachaka, sroto mukha vishodhaka. Tikta and katu rasa have laghu, ushna and tikshna properties, which are very useful for ama pachana. These also have deepana and pachana properties, which help in digestion of ama, restoration of agni, removal of excessive kledaka kapha and bringing of the pakva dosha to the kostha from the shakha. Laghu, Tikshna and Ruksha guna are Kaphashamaka. Ushna veerya is laghu and Vatakapha shamaka. Katu vipaka is laghu and Kaphaghna. Deepana,Pachana-Improve the state of Agni, help in Amapachana and cures Agnimandya. Shulagna relives the pain and Sotha hara relieves the inflammation.The components of Dhatri Bhallataka Vati help in Samprati vighatana by acting on causative factors of Amavata.

Conclusion

Dhatri Bhallataka Vati was taken from Rasatantra Sara va Siddha Prayoga Sangraha, Prathama Khanda, Gutika Prakarana. The chief ingredients of the formulation are ShuddhaBhallataka, Amalaki, Vibhitaki, Haritaki, Maricha, Pippali, Shunti, Guda and Tila. Dhatri Bhallataka Vati showed statistically extremely significant relief in Subjective parameters like Sandhi shoola, Sandhi sotha, Sandhi graha Morning stiffness and Sparsha asahatwa. Hence Dhatri Bhallataka Vati proved to be a beneficial drug in the management of Amavata. No complications or side effects were seen in the patients during or after the treatment.

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