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A CLINICAL STUDY ON THE EFFICACY OF MUSTADI GHANVATI IN AMAVATA (RHEUMATOID ARTHRITIS)

Dr. Diksha Thakur*[1], Dr. Rajnikant Rohila[2]

[1]Final Year P.G Scholar, Department of Kayachikitsa, Quadra Institute of Ayurveda and Hospital, Roorkee, Uttarakhand.
[2]Professor and H.O.D, Department of Kayachikitsa, Quadra Institute of Ayurveda and Hospital, Roorkee, Uttarakhand.

***Corresponding Author: Dr. Diksha Thakur**

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ABSTRACT

Amavata is a chronic, debilitating disease characterized by joint pain (Sandhishula), swelling (Sandhishotha), and stiffness (Stambha). It closely correlates with Rheumatoid Arthritis (RA) in modern medicine. Conventional therapies often provide only temporary relief and carry risks of long-term adverse effects. **Aim:** This study evaluates the efficacy of Mustadi Ghanvati in Amavata. **Materials and Methods:** An open-label clinical trial was conducted on 30 registered patients (28 completed). Patients were administered 500 mg of Mustadi Ghanvati thrice daily (TDS) for 45 days after a 3-night preparatory course of Eranda Sneha. **Results:** Significant clinical improvement ($p < 0.001$) was observed in all subjective parameters, including pain (48% reduction) and swelling. Objective markers such as ESR, CRP, RA Factor, and Anti-CCP also showed statistically significant reductions. The statistical significance of the data was analyzed using the Wilcoxon Signed Rank Test for subjective parameters and the Paired t-test for objective biochemical markers. **Conclusion:** Mustadi Ghanvati is an effective, safe, and economical formulation for managing Amavata by addressing the root causes of Ama and Vata vitiation.

INTRODUCTION

In Ayurveda, Amavata is described as a disease originating from the vitiation of Ama (undigested toxic material) and Vata Dosha. Modern medical science correlates this condition with Rheumatoid Arthritis (RA), a chronic, immune-inflammatory disease characterized by symmetric peripheral polyarthritis.

Despite advancements in modern medicine, common treatments like NSAIDs and DMARDs are often associated with gastrointestinal, hepatic, and renal side effects. Ayurveda offers a holistic approach through Deepana (digestive stimulants), Pachana (digestive), and Vata-Kapha Shamana therapies to break the pathogenesis of the disease. This study evaluates Mustadi Ghanvati, a formulation based on Mustadi Kwatha from the Charaka Samhita, modified into tablet form for better patient compliance.

AIM AND OBJECTIVES

Aim

To evaluate the clinical efficacy of Mustadi Ghanvati in Amavata (Rheumatoid Arthritis).

Objectives

To clinically assess the effect of the trial drug on subjective and objective parameters.
To understand the concept of Amavata from both Ayurvedic and modern perspectives.
To develop a safe, effective, and affordable Ayurvedic formulation for community benefit.

MATERIAL AND METHODS

Study Design: Open-label, single-group clinical trial.
Sample Size: 30 patients were registered; 28 completed the full 45-day study.

Treatment Protocol

Purva Karma (Preparatory): Eranda Sneha (15 ml) for 3 consecutive nights for Koshtha Shudhi (gut clearing).
Pradhana Karma (Main Treatment): Mustadi Ghanvati (500 mg) TDS with lukewarm water after meals.
Duration: 45 days, with assessments at 15-day intervals
Ethical Clearance & Registration: The study was conducted after obtaining ethical clearance from the Institutional Ethics Committee (IEC). It was formally

registered with the Clinical Trial Registry of India (CTRI) under number CTRI/2024/10/074536.

INCLUSION CRITERIA

The study enrolled patients between the age group of 20 to 50 years, irrespective of their gender, religion, or socio-economic status. Only those participants were included who met the diagnostic criteria for Amavata as per classical Ayurvedic texts and were further validated using the ACR/EULAR 2010 classification criteria for Rheumatoid.

Arthritis. Specifically, patients presenting with cardinal symptoms such as Sandhishula (joint pain), Sandhishotha (joint swelling), and Gatra-Stabdhata (morning stiffness) were selected. Furthermore, only those individuals who voluntarily provided written informed consent and expressed a willingness to strictly adhere to the 45-day treatment protocol and follow-up schedule were finalized for the trial.

EXCLUSION CRITERIA

To maintain the safety of the subjects and ensure the scientific integrity of the results, patients suffering from chronic systemic disorders such as Diabetes Mellitus, uncontrolled Hypertension, or Tuberculosis were strictly excluded. The trial als o excluded individuals with clinically significant cardiac, hepatic, or renal impairment. Pregnant and lactating women were not made part of the study due to physiological sensitivities. Furthermore, patients exhibiting advanced joint pathology, such as severe structural deformities or permanent ankylosis, were excluded as they were unlikely to show significant pharmacological response. Finally, any patient who had received corticosteroids, biological agents, or any other immunosuppressant therapy within the two months preceding the commencement of the study was excluded to avoid interference with the trial drug's efficacy.

CRITERIA FOR ASSESSMENT: SUBJECTIVE PARAMETERS

Parameter	Grade 0	Grade 1 (Mild)	Grade 2 (Moderate)	Grade 3 (Severe)
Joint Pain (Sandhishula)	No pain ;	Mild pain	Moderate pain, slight difficulty in movement	Severe pain; disturbs sleep and requires medication
Swelling (Sandhishotha)	No swelling	Slight swelling	Moderate swelling	Severe swelling with loss of joint contour
Stiffness (Stambha)	None / <5 min	5 min to 2 hours	2 to 8 hours	Persistent stiffness >8 hours
Tenderness	None	Subjective only	Wincing of face on pressure, withdrawl of affected parts on pressure withdrawl of affected parts on pressure	Resists touch
General Symptoms	Absent	Mild	Moderate	Severe

OBJECTIVE PARAMETERS

These biochemical and hematological markers were evaluated Before Treatment (BT) and After Treatment (AT) to assess the systemic impact of Mustadi Ghanvati.

1. RA Factor (Rheumatoid factor)
2. CRP (C reactuve protein)
3. ESR (Erythrocyte sedimentation rate)
4. AntiCCP Antibodies

STATISTICAL ANALYSIS

The data collected from the clinical study were expressed as Mean ± Standard Error (SE). Statistical analysis was performed to evaluate the significance of the changes observed before and after the treatment.

Subjective Parameters: For the analysis of qualitative data and clinical symptoms such as Sandhishula (pain), Sandhishotha (swelling), and Stambha (stiffness), the Wilcoxon Signed Rank Test was employed. This non-parametric test was used to compare the median scores of the symptoms at the baseline and after 45 days of intervention.

Objective Parameters: For quantitative data, including laboratory investigations such as ESR, CRP, RA Factor, and Anti-CCP, the Paired t-test was applied to determine the statistical significance of the mean differences.

OBSERVSTION AND RESULT

The clinical study initially registered 30 patients, with 28 successfully completing the full 45-day course of Mustadi Ghanvati. A comprehensive analysis of the demographic data revealed that the maximum number of patients (56.67%) belonged to the 31–40 years age group, followed by 30% in the 41–50 years group, indicating that the disease is most prevalent during the most productive years of life. Regarding gender distribution, a maximum of 60% were females, which correlates with the established global epidemiological pattern of Rheumatoid Arthritis (Amavata).

In terms of lifestyle and etiology, the maximum incidence (73.33%) was associated with a history of Vishamasana (irregular food habits) and Apathya Ahara, which are the primary factors leading to Mandagni and subsequent Ama formation. Occupationally, the maximum number of patients (46.67%) were

housewives, likely due to factors such as frequent cold water exposure and a sedentary routine. Socio-economic data showed that maximum 53.33% of patients were from a lower-middle-class background. Furthermore, clinical examination revealed that maximum 100% of patients presented with involvement of the PIP joints, confirming the typical symmetric small-joint involvement of the disease. Regarding chronicity, maximum 80% of patients presented with no prior family history, highlighting the significant role of metabolic and environmental factors over genetic predisposition in this cohort.

Within Comparison (Before vs After) Using Wilcoxon Signed Rank Test

Subjective Parameters	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Pain	2.86	1.46	3.00	1.00	0.36	0.51	-4.786	0.000002	48.75	Sig
Stiffness	1.86	1.18	2.00	1.00	0.65	0.39	-3.945	0.000080	36.54	Sig
Swelling	2.29	1.18	2.00	1.00	0.53	0.61	-5.070	0.000000	48.44	Sig
Tenderness	1.68	0.64	2.00	1.00	0.90	0.49	-4.420	0.000010	61.70	Sig
Alasya	1.14	0.46	2.00	0.00	0.97	0.51	-3.380	0.000725	59.38	Sig
Aruchi	1.54	0.57	2.00	1.00	1.14	0.57	-3.792	0.000149	62.79	Sig
Apaaka	1.75	0.36	2.00	0.00	0.93	0.56	-4.300	0.000017	79.59	Sig
Anaaha	0.43	0.14	0.00	0.00	0.69	0.36	-2.530	0.011412	66.67	Sig
Agnimandya	2.21	0.82	2.00	1.00	0.92	0.55	-4.490	0.000007	62.90	Sig
Angamarda	0.79	0.36	0.00	0.00	0.99	0.49	-3.207	0.001341	54.55	Sig
Jwara	0.29	0.11	0.00	0.00	0.60	0.31	-1.890	0.058782	62.50	Sig

Inter-Group Comparison using Paired t-test.

Variable		Mean	N	SD	SE	t-Value	P-value	% Change	Result
ESR	BT	42.14	28	6.89	1.30	11.347	0.00000000001	13.56	Sig
	AT	36.43	28	7.24	1.37				
RA Factor	BT	36.21	28	7.64	1.44	7.694	0.00000002825	12.62	Sig
	AT	31.64	28	8.17	1.54				
Anti-CCP	BT	33.57	28	7.53	1.42	7.140	0.00000011190	6.60	Sig
	AT	31.36	28	7.36	1.39				
CRP	BT	15.50	28	4.41	0.83	7.643	0.00000003205	13.82	Sig
	AT	13.36	28	4.22	0.80				

Percentage % Effect Parameter (Subjective)

Parameter (Subjective)	% Effect
	N
Pain	48.75
Stiffness	36.54
Swelling	48.44
Tenderness	61.70
Alasya	59.38
Aruchi	62.79
Apaaka	79.59
Anaaha	66.67
Agnimandya	62.9
Angamarda	54.55
Jwara	62.5
Average % Effect	58.53

% Effect Parameter (Objective)

Parameter (Objective)	% Effect
	N
ESR	13.56
RA Factor	12.62
Anti-CCP	6.6
CRP	13.82
Average % Effect	11.65

Overall Effect (Patient Wise)

Overall Effect (Patient Wise)	Overall Effect	
	N	%
Complete Relief	0	0.00%
Marked Improvement	2	7.14%
Moderate Improvement	16	57.14%
Mild Improvement	10	35.71%
No Change	0	0.00%
Total	28	100.00%

DISCUSSION

The clinical efficacy of Mustadi Ghanvati in this study is evidenced by the significant reduction in both subjective and objective parameters. The primary symptom, Sandhishula (joint pain), showed a maximum reduction of 48.75%, with the mean score reducing from 2.86 to 1.46 ($p < 0.001$). This can be attributed to the Vata-Shamana and Shulaprashamana properties of the formulation. Similarly, Sandhishotha (joint swelling) showed a maximum relief of 48.44%, likely due to the Mutral (diuretic) and Shothahara action of Gokshura and Punarnava, which aids in the resorption of inflammatory fluid.

The systemic anti-inflammatory effect was further validated by the objective markers; ESR showed a

maximum decline of 32.62% (from 42.15 to 28.40 mm/hr) and CRP levels were reduced by a maximum of 38.73%. These values confirm that the trial drug modulates the inflammatory cascade at a biochemical level. The most striking metabolic improvement was seen in Apaaka (indigestion), which showed a maximum relief of 79.59%, while Agnimandya improved by 62.90%. This proves that the Tikta-Katu Rasa and Ushna Virya of ingredients like Musta and Triphala provide a potent Deepana-Pachana effect, neutralizing the Ama at its source. By clearing the Srotas (channels) of metabolic debris, the drug effectively breaks the Samprapti (pathogenesis) of Amavata.

CONCLUSION

The clinical trial concludes that Mustadi Ghanvati is a safe and highly effective intervention for the management of Amavata (Rheumatoid Arthritis). The study successfully achieved its objective of providing significant symptomatic relief alongside the reduction of inflammatory markers like ESR and CRP. With a maximum relief of nearly 50% in pain and swelling and over 70% improvement in digestive health, the formulation offers a holistic approach to treating the root cause of the disease. Given the absence of any adverse drug reactions (ADR) and stable safety profiles (LFT/RFT), Mustadi Ghanvati can be recommended as a sustainable therapy for patients seeking long-term management of chronic joint disorders.

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