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A RANDOMIZED CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFECT OF *VEDANASTHAPANA MAHAKASHAYA PARISHEKA* ON PAIN PARAMETER IN *AMAVATA* W.S.R. TO RHEUMATOID ARTHRITIS

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ABSTRACT

Amavata is a classical *Amaja Vyadhi* characterised by the concomitant vitiation of *Ama* and *Vata Dosha*, which, if untreated, progressively involves deeper *dhatu* and impairs joint function. The primary etiological factors include *Viruddha Ahara* and improper lifestyle, leading to the formation of *Ama*. This *Ama*, in combination with aggravated *Vata*, localises in the joints, producing hallmark clinical features such as *Sandhi Shoola*, *Stabdhata*, and *Sandhi Shopha*. Ayurvedic texts emphasise therapeutic interventions including *Langhana*, *Swedana*, *Deepana*, and the application of *Katutikta Dravya*. *Ruksha Swedana*, in particular, is advocated for *Amavata*, addressing both *Ama* and *Vata* vitiation. From a modern biomedical perspective, *Amavata* is often correlated with rheumatoid arthritis (RA), a chronic autoimmune inflammatory disorder characterised by symmetric polyarthritis, systemic manifestations, and progressive joint deformities. As RA is incurable, effective pain management remains essential to

improve functional capacity and quality of life, particularly in middle-aged individuals. *Swedana* is one of the principal treatment modalities advocated in the management of *Amavata*. *Vedanasthapana Mahakashaya* possesses analgesic and anti-inflammatory properties and may provide effective symptomatic relief when administered as *Parisheka Sweda.* **Aim:** To evaluate and compare the efficacy of *Vedanasthapana Mahakashaya Parisheka* and *Twak Patra Parisheka* on pain parameters in patients suffering from *Amavata* w.s.r. to Rheumatoid Arthritis. **Materials and Methods:** A randomized open-label comparative clinical trial was conducted on 30 patients diagnosed with Amavata fulfilling diagnostic criteria. Patients were randomly allocated into two groups of 15 each. Group A received *Twak Patra Parisheka* and Group B received *Vedanasthapana Mahakashaya Parisheka* for 30 minutes daily for seven consecutive days. **Results:** Both interventions produced statistically significant improvements in pain and associated symptoms. *Vedanasthapana Mahakashaya Parisheka* demonstrated superior improvement in VAS, VRS, NRS, and painDETECT scores compared to *Twak Patra Parisheka*. **Conclusion:** *Vedanasthapana Mahakashaya Parisheka* was found to be more effective than *Twak Patra Parisheka* in reducing pain and improving clinical manifestations of *Amavata*.

KEYWORDS: *Amavata*, *Vedanasthapana Mahakashaya Parisheka*, *Twak Patra Parisheka*, *Swedana*, Rheumatoid Arthritis, Pain Management.

INTRODUCTION

Amavata is a complex and debilitating disorder described in Ayurveda, characterized by the simultaneous vitiation of *Ama* (metabolic toxin) and *Vata dosha*, resulting in joint stiffness, swelling, pain, and restricted movement. It is often equated with *Rheumatoid Arthritis (RA)* in modern medical science due to its similar symptomatology and chronic, progressive nature. The primary etiological factors of *Amavata* include *viruddha ahara* (incompatible diet) and *viruddha vihara* (improper lifestyle), leading to impaired digestion (*agnimandya*) and accumulation of *ama*, which when combined with aggravated *vata*, localizes in the joints (*sandhi*), producing pain and stiffness.[1]

Rheumatoid Arthritis, a chronic autoimmune inflammatory disease, manifests as symmetrical polyarthritis, predominantly affecting the small joints of the hands and wrists. The disease exhibits systemic features involving the skin, eyes, lungs, and cardiovascular system.[2] Global epidemiological data suggest that approximately 0.5–1% of adults worldwide are affected, with a higher prevalence in females (2.5:1) and onset typically between 30 and 50

years of age.[3] The chronicity, progressive joint destruction, and limited curative options in RA underscore the need for effective, safe, and affordable treatment modalities that can alleviate pain, improve function, and enhance the quality of life.[4]

In Ayurvedic therapeutics, *Swedana* is one of the *Shadupakrama* mentioned for the management of *Amavata*. *Swedana* acts by relieving stiffness (*stambha*), heaviness (*gourava*), and coldness (*sheetata*) through induction of perspiration and removal of toxins.[5] Among the various types of *Swedana*, *Parisheka Sweda* i.e. *drava sweda* involves the pouring of warm medicated decoction over the body to achieve localized or systemic sweating. For *Amavata*, *rooksha sweda* (dry sudation) is particularly indicated during the *Amaja* stage to counteract *kapha* and *ama* dominance.[6]

The *Vedanasthapana Mahakashaya* mentioned in *Charaka Samhita* comprises ten drugs—*Shala, Katphala, Kadamba, Padmaka, Tumba, Mocharasa, Sirisha, Vetasa, Elavaluka, and Ashoka*—renowned for their *tikta* and *kashaya rasa* and *laghu-rooksha guna*, providing *pitta-kapha shamana*, *ama pachana*, and *shothahara* (anti-inflammatory) properties.[7] These herbs are pharmacologically recognized for their analgesic, anti-inflammatory, and antioxidant actions, making them ideal candidates for pain management in *Amavata*.

Twak Patra (Cinnamomum zeylanicum), on the other hand, possesses *katu-tikta-madhura rasa*, *ushna virya*, and *kapha-vata hara* properties, which promote local circulation, reduce stiffness, and provide pain relief.[8] Comparative evaluation of *Vedanasthapana Mahakashaya Parisheka* (VSMP) and *Twak Patra Parisheka* (TPP) in the management of *Amavata* thus holds clinical relevance in identifying a superior therapeutic approach for symptoms alleviation.

MATERIAL AND METHODS

Ethical clearance and CTRI registration: Ethics clearance certificate was obtained from institutional ethics committee. Trial was registered and completed in www.ctri.gov.in under CTRI no. CTRI/2024/10/075221

Source of Data

Drug source

- ***Vedanasthapana mahakashaya qwatha***- *Vedanasthapana mahakashaya qwatha* drugs are obtained from Sri Dharamsthala Manjunatheswara Ayurveda Pharmacy, Kuthpady, Udupi.

- ***Twak patra qwatha***- The leaves of *Twak* are procured from local area of Udupi and certified from Dravyaguna department of Sri Dharamsthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi.

Patient source: 30 Patients attending OPD & IPD of Sri Dharamsthala Manjunatheshwara Ayurveda Hospital, Udupi fulfilling the inclusion criteria are selected for the study.

Study Design: The present clinical study was designed as an open-label, randomized, comparative clinical trial with a pre-test and post-test design. A total of 30 patients diagnosed with *Amavata* based on diagnostic criteria were enrolled from the OPD and IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. Patients were randomly allocated into two groups—Group A (TPP) and Group B (VSMP)—each comprising 15 patients. The study followed ethical guidelines, and all participants provided informed consent.

Inclusion criteria	**Exclusion criteria**
Patients aged between 18 and 70 years fulfilling the diagnostic criteria of *Amavata*.	Patients with systemic illnesses like uncontrolled diabetes mellitus, hypertension, or other severe disorders
Freshly diagnosed cases without prior treatment.	Pregnant women
Patients fit for *Parisheka Swedana*	Lactating women

Diagnostic Criteria

- Presence of *sandhi shoola* (joint pain) along with at least three *samanya lakshanas* of *Amavata* such as *angamarda* (body ache), *aruchi* (anorexia), *trishna* (thirst), *alasya* (fatigue), *gourava* (heaviness), *jwara* (fever), *apaka* (indigestion), and *sandhi shotha* (joint swelling).
- ACR/EULAR 2010 revised criteria for RA with a score ≥6.

Interventions

- **Group-A (Control group):** *Twak Patra Parisheka* (TPP) was administered without *abhyanga* (massage) for 30 minutes once daily for 7 consecutive days. Decoction temperature was maintained between 38–42°C as per patient tolerance.

- **Group-B (Trial group):** *Vedanasthapana Mahakashaya Parisheka* (VSMP) was administered without *abhyanga* for 30 minutes once daily for 7 days at the same temperature range.

Duration of Study

- Treatment period: 7 days
- Follow-up: 7 days post-treatment
- Total study duration per patient: 14 days

Assessment Criteria: Patients were assessed on both subjective and objective parameters before treatment (0th day), after treatment (7th day), and on follow-up (14th day).

Subjective Parameters

- *Sandhi Shoola* (pain): Visual Analogue Scale (VAS), Verbal Rating Scale (VRS), Numerical Rating Scale (NRS), and painDETECT questionnaire.
- *Samanya Lakshanas* of *Amavata*: *Angamarda, Aruchi, Trishna, Gourava, Apaka, Alasya, Jwara, Stabdhata*.
- *Samyaka Swinna Lakshanas*: *Sheeta vyuparama, Shoola vyuparama, Stambha nigraha, Gourava nigraha, Angamardava.*

Objective Parameters

- *Sandhi Shotha* (joint swelling)
- *Sweda Srava* (perspiration)
- RA factor, C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR).

OBSERVATIONS

Table 1: Demographic and disease related observations.

Parameters	Observations	Maximum patients	Percentage
Age	51-60 Years	11	36.66
Sex	Female	24	80.00
Appetite	Reduced	20	66.66
Koshta	*Madhyama*	19	63.33
Nature of Work	Walking	16	53.33
Vikruti-Dosha	*Vata Kapha*	30	100.0
Vikruti-Dhatu	*Rasa Rakta Mamsa Meda Asthi*	30	100.0
Ahara Shakti - Abhyavarana	*Avara*	20	66.66
Ahara Shakti - Jarana	*Avara*	20	66.66
Vaya	*Madhyama*	25	83.33

Observation related to *Samyak swinna lakshana:* These symptoms were assessed after 30 minutes of treatment in all the patients daily. Symptoms like *sweda pradurbhava,*

mardavata are observed daily in almost all the patients. *Sheeta* and *shoola vyuparama* were seen as reduced severity of symptoms daily in all the patients. *Stambha* and *gaurava nigraha* was observed in patients having those symptoms and assesses as reduced severity of symptoms daily. No patient developed *ati or aswinna lakshana.*

RESULT

In this study, *Twak Patra Parisheka* (TPP) and *Vedanasthapana Mahakashaya Parisheka* (VSMP) were done in 30 patients of *Amavata*, 15 patients in each group. The relevant data was collected before and after the treatment. The collected data was analyzed using Wilcoxon Signed Rank Test, Paired t-test for within the group and Unpaired t-test, Mann-Whitney U test for between the groups. After the treatment each group showed statistically significant improvement in the parameters selected for the study. The different values are given in table no. 2, 3, 4 and 5.

Table No. 2: Statistical analysis of Subjective Parameters within the group.

Subjective Parameters		Mean			% Of Relief	Standard Deviation		Standard Error		Median		Z value	p value	Interpretation
		BT	AT	BT-AT		BT	AT	BT	AT	BT	AT			
VAS	**TPP**	8.46	6.13	2.33	27.5	1.24	1.24	0.32	0.32	9.0	6.0	-3.57	0.0003	HS
	VSMP	8.40	2.00	6.40	76.1	1.29	0.65	0.33	0.16	8.0	2.0	-3.45	0.001	HS
VRS	**TPP**	4.06	3.00	1.06	26.2	0.59	0.65	0.15	0.16	4.0	3.0	-3.77	0.0001	HS
	VSMP	4.13	1.13	3.00	72.5	0.74	0.35	0.19	0.09	4.0	1.0	-3.49	0.0004	HS
NRS	**TPP**	8.46	6.13	2.33	27.5	1.24	1.24	0.32	0.32	9.0	6.0	-3.57	0.0003	HS
	VSMP	8.40	1.93	6.46	76.9	1.29	0.70	0.33	0.18	8.0	2.0	-3.44	0.001	HS
pain DETECT	**TPP**	0.80	0.53	0.26	33.3	1.47	0.91	0.38	0.23	0.0	0.0	-1.41	0.157	NS
	VSMP	1.33	0.13	1.20	90.0	1.04	0.51	0.27	0.13	2.0	0.0	-2.80	0.005	S
Stabadagatrata	**TPP**	1.13	0.46	0.66	58.8	1.12	0.51	0.29	0.13	2.0	0.0	-2.64	0.008	S
	VSMP	1.66	0.60	1.06	64.0	0.89	0.50	0.23	0.13	2.0	1.0	-3.17	0.001	HS
Angamarda	**TPP**	2.60	1.40	1.20	46.1	0.63	0.63	0.16	0.16	3.0	1.0	-3.62	0.0002	HS
	VSMP	2.86.	0.66	2.20	76.7	0.74	0.48	0.19	0.12	3.0	1.0	-3.53	0.0004	HS
Aruchi	**TPP**	2.00	0.93	1.06	53.3	1.00	0.70	0.25	0.18	2.0	1.0	-3.35	0.001	HS
	VSMP	1.93	0.20	1.73	89.6	1.03	0.41	0.26	0.10	2.0	0.0	-3.34	0.001	HS
Trushna	**TPP**	0.06	0.06	0.00	0.0	0.25	0.25	0.06	0.06	0.0	0.0	0.0	1.000	NS
	VSMP	0.06	0.00	0.06	100	0.25	0.00	0.06	0.00	0.0	0.0	-1.00	0.317	NS
Alasya	**TPP**	2.26	1.13	1.13	50.0	0.70	0.51	0.18	0.13	2.0	1.0	-3.35	0.001	HS
	VSMP	2.60	0.53	2.06	79.4	0.91	0.51	0.23	0.13	3.0	1.0	-3.40	0.001	HS
Gourava	**TPP**	2.26	1.13	1.13	50.0	0.63	0.59	0.16	0.15	3.0	1.0	-3.41	0.001	HS

	VSMP	2.60	0.53	2.06	79.4	0.63	0.53	0.16	0.13	3.0	1.0	-3.27	0.001	HS
Jwara	**TPP**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.0	0.00	1.000	NS
	VSMP	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.0	0.00	1.000	NS
Apaka	**TPP**	1.53	0.53	1.00	65.2	0.83	0.51	0.21	0.13	2.0	1.0	-3.21	0.001	HS
	VSMP	1.53	0.20	1.33	86.9	1.12	0.41	0.29	0.10	2.0	0.0	-2.98	0.003	S
Sandhishotha	**TPP**	0.46	0.33	0.13	28.5	0.74	0.48	0.19	0.12	0.0	0.0	-1.41	0.157	NS
	VSMP	0.33	0.13	0.20	60.0	0.48	0.35	0.12	0.90	0.0	0.0	-1.73	0.083	NS

Table No. 3: Statistical analysis of Objective Parameters within the group.

Objective Parameters		**Mean**			**% Of Relief**	**Standard Deviation**		**Standard Error**		**Median**		**'t' value**	**p value**	**Interpretation**
		BT	**AT**	**BT-AT**		**BT**	**AT**	**BT**	**AT**	**BT**	**AT**			
RA	**TPP**	66.3	58.0	8.38	12.6	46.0	34.6	11.8	8.93	53.7	49.8	2.38	0.032	S
	VSMP	90.5	84.9	5.60	6.19	140.0	121.5	36.1	31.3	38.7	36.6	0.81	0.429	NS
CRP	**TPP**	27.5	15.7	11.8	42.7	34.4	17.7	8.89	4.59	10.9	7.90	2.256	0.041	S
	VSMP	25.0	19.4	5.56	22.2	29.8	31.5	7.71	8.14	7.50	5.30	0.823	0.425	NS
ESR	**TPP**	50.4	42.8	7.66	15.1	24.2	19.3	6.25	5.00	40.0	37.0	3.061	0.008	S
	VSMP	46.6	42.0	4.53	9.72	32.5	31.3	8.41	8.09	39.0	31.0	0.008	0.402	NS

Table No. 4: Statistical analysis of Subjective Parameters between the groups.

Subjective Parameters	**Group**	**Mann Whitney U Test**			**U Value**	**Z Value**	**p Value**	**Interpretation**
		N	**Mean Rank**	**Sum of Rank**				
VAS	**TPP**	15	8.00	120.00	0.000	-4.826	0.000001	HS
	VSMP	15	23.00	345.00				
VRS	**TPP**	15	8.10	121.50	1.500	-4.939	0.000007	HS
	VSMP	15	22.90	343.50				
NRS	**TPP**	15	8.00	120.00	0.000	-4.819	0.000001	HS
	VSMP	15	23.00	345.00				
pain DETECT	**TPP**	15	12.0	180.00	60.000	-2.567	0.010	S
	VSMP	15	19.0	285.0				
Stabadagatrata	**TPP**	15	13.23	198.50	78.500	-1.526	0.127	NS
	VSMP	15	17.77	266.50				
Angamarda	**TPP**	15	9.60	144.00	24.000	-4.015	0.00005	HS
	VSMP	15	21.40	321.00				
Aruchi	**TPP**	15	12.53	188.00	68.000	-2.022	0.043	S
	VSMP	15	18.47	277.00				
Trushna	**TPP**	15	15.00	225.00	105.00	-1.000	0.317	NS
	VSMP	15	16.00	240.00				
Alasya	**TPP**	15	10.80	162.00	42.000	-3.088	0.002	HS
	VSMP	15	20.20	303.00				
Gourava	**TPP**	15	13.80	207.00	87.000	-1.156	0.248	NS
	VSMP	15	17.20	258.00				
Jwara	**TPP**	15	15.50	232.50	112.500	0.000	1.000	NS

	VSMP	15	15.50	232.50				
Apaka	**TPP**	15	14.10	211.50	91.500	-0.925	0.355	NS
	VSMP	15	16.90	253.50				
Sandhishotha	**TPP**	15	15.00	225.00	105.00	-0.482	0.630	NS
	VSMP	15	16.00	240.00				

Table No. 5: Statistical analysis of Objective Parameters between the group.

Objective Parameters		**N**	**MEAN DIFFERENCE**	**Unpaired 't' test**				**Interpretation**
				S.D.	**S.E.M**	**'t' Value**	**P Value**	
RA	**TPP**	15	8.38667	13.64006	3.52185	0.360	0.722	NS
	VSMP	15	5.60667	26.66052	6.88372			
CRP	**TPP**	15	11.80000	20.25558	5.22997	0.729	0.472	NS
	VSMP	15	5.56667	26.21029	6.76747			
ESR	**TPP**	15	7.66667	9.70027	2.50460	0.539	0.594	NS
	VSMP	15	4.53333	20.31842	5.24619			

DISCUSSION

The study demonstrated that both *Twak Patra Parisheka* and *Vedanasthapana Mahakashaya Parisheka* are beneficial in alleviating pain and associated symptoms of *Amavata*. However, VSMP showed superior efficacy across all pain parameters and several associated *lakshanas*, signifying its stronger *vedanasthapana* (analgesic) and *shothahara* (anti-inflammatory) properties.

Mechanism of Action-Ayurvedic View

Swedana works through four principal actions—*sthambhaghna, gouravaghna, sheetaghna,* and *swedakaraka*—collectively relieving stiffness, heaviness, and coldness. The heat from *Parisheka* liquefies *ama* and opens obstructed *srotas*, facilitating *dosha draveekarana* and *vata shamana*. The medicated decoction further acts locally through its *virya* and *guna*, enhancing *agni deepana* and promoting *sandhi chesta vriddhi* (joint mobility).

Pharmacodynamic Explanation

- The *tikta* and *kashaya rasa*, *laghu-rooksha guna*, and *sheeta/ushna virya* of *Vedanasthapana Mahakashaya* drugs enable dual action—ameliorating both *vata* and *pitta*-related pain.

- Phytoconstituents like tannins, myricetin, and pentosin contribute to anti-inflammatory, antioxidant, and analgesic effects.

- *Twak Patra*, though effective, primarily acts via *ushna virya* and circulatory enhancement, providing symptomatic relief but less potent systemic effect than the multicomponent *Vedanasthapana Mahakashaya* combination.

Physiologically, *Swedana* induces vasodilation, enhances blood flow, reduces muscle tension, and increases pain threshold. Heat improves tissue extensibility and promotes metabolic activation, aiding in toxin clearance. These effects align with modern heat therapy principles used in RA for pain reduction and mobility improvement.

Clinical Interpretation

The statistically significant pain reduction in the VSMP group underscores its potential as an effective adjuvant therapy in *Amavata/RA*. The observed mild improvement in inflammatory markers (CRP, ESR) supports its systemic influence, while the absence of adverse reactions confirms its safety profile. The difference in laboratory parameters' statistical insignificance may be attributed to the short treatment duration and limited sample size.

CONCLUSION

The comparative clinical evaluation of *Vedanasthapana Mahakashaya Parisheka* (VSMP) and *Twak Patra Parisheka* (TPP) revealed that both interventions effectively reduced pain and stiffness in *Amavata*, but *Vedanasthapana Mahakashaya Parisheka* demonstrated superior efficacy on multiple parameters, including VAS, VRS, NRS, painDETECT, *angamarda*, *aruchi*, and *alasya*.

- In **Group A (TPP):** 20% patients showed mild improvement, 80% remained unchanged.
- In **Group B (VSMP):** 53.34% showed mild improvement, 13.34% moderate improvement, and 33.34% unchanged.
- **No adverse events** were observed in either group, indicating safety and tolerability.

Thus, *Vedanasthapana Mahakashaya Parisheka* can be considered more efficacious in pain management and functional improvement in *Amavata* compared to *Twak Patra Parisheka*. The enhanced efficacy is likely due to the synergistic *vedanasthapana*, *vata-shamana*, and *shothahara* actions of the ten-drug combination, offering both local and systemic benefits. However, the small sample size and short duration of intervention limit the generalizability of findings. Future studies should employ larger multicentric trials, longer treatment durations and objective imaging or biochemical correlates to validate and expand upon these outcomes. Additionally, mechanistic studies exploring the biochemical pathways influenced by

Parisheka Sweda could elucidate its physiological basis and strengthen its position as a scientifically validated Ayurvedic therapy for *Amavata* and related rheumatologic disorders.

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