A RANDOMIZED CLINICAL STUDY TO EVALUATE THE EFFECT OF DHANYAMLA PARISHEKA AND TWAK NIRGUNDI PARISHEKA ON PAIN PARAMETER IN AMAVATA W.S.R TO RHEUMATOID ARTHRITIS

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ABSTRACT

Sandhi Shoola is the symptoms which make the patient to compromise his/ her physical, psychological, social efficiencies. Among them, *amavata* is most common condition where the involvement of *vata* and *ama* is evident by the symptoms like *sandhi soola, sandhi stabdhata.* Amoung the therapeutic measures *rooksha swedana* is advocated for management of pain and alleviating other symptoms due to *amadosha. Dhanyamla, Twaka patra, nirgundi patra* are common durgs indicated for *parisheka* as having *vatakaphapaham, sholahara, ushna, rooksha, strotoshodhana* properties. Considering this *twak nirgundi parisheka* and *dhanyamla parisheka* can be used for treatment of *amavata.* Present study was an open label comparative clinical study where 30 patients of *amavata* were randomly treated with *Dhanyamla parisheka* and *Twak Nirgundi parisheka* daily 30 minutes for 7 days. the study showed Both *Dhanyamladhara* and *Twaka Nirgundi Parisheka* statistically significant improvement pain parameter and no difference on in between group comparision.

KEYWORDS*:* Amavata, Dhanyamlad Parisheka, Twaka Nirgundi Parisheka, Sandhi Shoola.

INTRODUCTION

Pain in significantly impacts daily life, limiting mobility and hampering quality of life. Addressing this pain is crucial to prevent long-term joint damage, enhance function, and improve overall well-being.

Amavata is one such *saam vata vyadhi* which is pain predominant and characterized by the predominance *sandhi soola*, *sandhi stabdhat*, *Angamardha, aruchi, trushna, alasya, gourava, jwara, apaka, sandhi shotha*.[1] A lack of public understanding of ama often results in repeated engagement in *nidhana*, causing the accumulation of *ama* in the body, carried by *dooshitha vaata,* leading to *stabdhatha* and *gurutha* in *santhi*. This process produces symptoms mirroring those of *amavaata* on *sthaanasamshraya*, such as *Angamarda, aruchi, trushna, aalasya, gaurava, jwara, apaaka,* and *shoonatha*, closely aligning with the set of symptoms described for rheumatoid arthritis.[2]

Rheumatoid arthritis, characterized by chronic inflammatory autoimmune disruption impacting the functional and anatomical aspects of joints, is a global health concern. The prevalence of rheumatoid arthritis worldwide is currently estimated at 460 cases per 100,000 individuals, exhibiting an alarming upward trend. In India, the prevalence rate is 7.5%, with a notable threefold higher occurrence in females compared to males. The concerning aspect is the increasing manifestation of this condition in the working-class population between the ages of 30 and 60, leading to a reduction in productivity.

Recommend therapeutic measures like *Langhana, Swedana, Katu Tikta dravya prayoga*, and *Deepana* are explained for managing Amavata.[3] In its management, *rooksha sweda* is the preferred modality of *bahirparimarjana chikitsa* specially to manage symptoms *amavata* is preset in all joints so *sarvanga sweda* is selected for procedure with is *rooksha* in order to alleviate *ama*. *Dhanyamla* is *ushna, rooksha*, and *teekshna gunas*, predominantly produces the *rooksha swedana* having *amahara* and *vatahara* properties.[4]

Additionally, twak is recognized for its *kapha-vata shamana* property and *Nirgundi* is known for its *vatasleshmahara* properties, also possesses *amavatahara* qualities. Therefore, both *twak nirgundi parisheka* and *dhanyamla parisheka* are viable treatment options for *Amavata.*

MATERIALS 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/2021/04/042426

Source of data

Drug source

- ***Dhanyamla*:** The drugs used to prepare *dhanyamla* were procured from in and around Udupi and *Dhanyamla* was prepared in the Panchakarma treatment unit.

- ***Twak nirgundi kwatha:*** The leaves of *twak*[5] and *nirgundi*[6] were procured from in and around Udupi and *twak nirgundi kwatha* was freshly prepared daily in the Panchakarma treatment unit.

Patient source

30 Patients of *amavata* were selected for the study from OPD & IPD of SDM Ayurveda Hospital, Udupi.

Method of collection of data

Study design

This is an open label comparative clinical study with pre-test and post-test design where minimum 30 patients of Rheumatoid Arthritis of either gender were selected based on diagnostic and inclusion criteria and randomly distributed between *Dhanyamla parisheka* and *Twak Nirgundi parisheka* group.

Sample size

30 patients diagnosed as *amavata* were selected for the study.

Diagnostic criteria

- ***Lakshanas* of *Amavata*:** *sandhi soola*, *sandhi stabdhat* with any one or more symptoms like *Angamardha, aruchi, trushna, alasya, gourava, jwara, apaka, sandhi shotha*.

- **2010 ACR Revised criteria[7]**

Inclusion Criteria

- Patients fulfilling the diagnostic criteria

- Patients aged between 18-70 years.

- Patients fit for *swedana*.

Exclusion Criteria

- Patients with systemic illness: Diabetes mellitus and Hypertension.

- All connective tissue disorders other than Rheumatoid arthritis.

Duration Of trearment: 7 days

Follow Up: 7 Days

Total Duration Of Study: 14 days

INTERVENTION

Selected 30 patients were randomly allotted into group A and group B (15 patients in each group)

GROUP A

In the selected group *Dhanyamla parisheka* was done for 30 minutes. The temperature of the *dhanyamla* was maintained between 34-40 degree Celsius for 7 days. Daily fresh *dhanyamla* was used.

GROUP B

In the selected group *Twak nirgundi parisheka* was done for 30 minutes. The temperature of the *twaka nirgundi kwatha* was maintained between 34-40 degree Celsius for 7 days. Daily fresh *Twak nirgundi kwatha* was prepared.

Assessment criteria

In each patient pain was assessed before (day 0) and after (day 7) and on the day of follow up (day 14) based on subjective and objective parameters. The observations and assessment were recorded in specially prepared case proforma.

Subjective Parameters

- **Lakshanas of *Amavata*:** Sandhi shoola
- **The level of pain will be assessed in rheumatoid arthritis using**
1. Visual Analogue Scale[8]
2. Rheumatoid Arthritis Pain Scale[9]
3. McGill Pain Questionnaire[10]
4. PAINDETECT[11]
5. SF-36 total score[12]

- ***Samyak swinna lakshana:*** *anga mardava, gaurava nigraha, sheetha vyuparama, shoola vyuparama, stambha nigraha.*

Objective Parameters

- ***Lakshanas of Amavata:*** *sandhi shotha and stabhadhata*
- ***Samyak swinna lakshana:*** *sweda pradurbhava*
- RA factor
- CRP level
- ESR level

OBSERVATIONS

In the present study, 30 patients of *amavata* were treated with *dhanyamla parisheka* and *twaka nirgundin parisheka*, 15 patients in each group.

Total number of patients registered for the study: 30

Number of patients completed the study: 30

Dropouts: nil

Some of the observations are as follows Table no. 1, 2

Table 1: Demographic observations.

Parameters	Observations parameter In each	Maximum patients	Percentage
Age	61-70 Years	11	36.7
Sex	Female	19	63.3
Occupation	Housewife	17	56.7
Marital Status	Married	30	100.0
Desha	*Anupa*	26	86.7
Prakruti	*Vata Kapha*	13	43.3

Table 2: Observations related to disease.

Vikruti	*Vata Kapha*	21	70.0
Dhatu	*Rasa Rakta Mamsa Meda*	21	70.0
Agni	*Mandagni*	22	73.3
Koshta	*Madhyama*	15	50.0
Duration of Disease	Less Than 1 Year	8	26.7
	3-5 years	8	26.7
Treatment History	No Previous History	19	63.3

Observatoion 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, *dhanyamla parisheka* and *twaka nirgundi parisheka* was done in 30 parients of amavata, 15 patients in each group. The relevant data was collected before and after the treatment. The collected data was analysed using Wilcoxon Signed Rank Test, Paired t-test, Unpaired t-test, mann-whitney u test.

After the treatmet each group showed statistically significant improvement in the parameters selected for the study. The different values are givenin table no.3,4,5,6 and 7.

Table no. 3: statistical analysis of observed result for subjective parameters.

		WILCOXON SIGNED RANK TEST					
		DHANYAMLA PARISHEKA			*TWAKA NIRGUNDI PARISHEKA*		
Sl. No	Symptomatic variables	Before treatment (Mean)	After treatment (Mean)	Reduction Percentage	Before treatment (Mean)	After treatment (Mean)	Reduction Percentage
1	*Sandhishoola*	3.4000	1.3333	60.7852%	3.5333	1.4000	60.3769%
2	*Sandhistabdhata*	2.3333	1.6000	31.4275%	2.0667	1.0000	51.6136%
3	ACR Revised Criteria	7.0667	6.5333	7.5480%	6.7333	6.6000	1.9797%
4	Visual Analogue Scale	8.2667	4.5333	45.1619%	8.1333	6.4000	21.3111%
5	painDETECT	30.6000	20.2667	33.7689%	30.8000	19.2000	37.6623%
6	Rheumatoid Arthritis Pain Scale	89.4000	59.4000	33.5570%	92.4667	50.7333	45.1334%
7	SF-36 total score	40.2000	68.4667	-70.3151%	46.8000	75.9333	-62.2506%

Table no. 4: Statistical analysis of objective parameters.

		Wilcoxon Signed Rank Test									
Parameter	Treatmengroup	Negative ranks			Positive Ranks			Tie	Zvalue	P value	Interpreta-tion
		N	MR	SR	N	MR	SR				
Sandhishoola	DN BT-AT	15	8.00	120.00	-	-	-	-	-3.453	0.001	HS
	TN BT-AT	15	8.00	120.00	-	-	-	-	-3.464	0.001	HS
Sandhistabdhata	DN BT-AT	10	5.50	55.00	-	-	-	5	-3.051	0.002	S
	TN BT-AT	14	7.50	105.00	-	-	-	1	-3.557	0.000	HS

ACR Revised Criteria	DN BT-AT	7	4.00	28.00	-	-	-	8	-2.530	0.011	S
	TN BT-AT	2	1.50	3.00	-	-	-	13	-1.414	0.157	NS
Visual Analogue Scale	DN BT-AT	15	8.00	120.00	-	-	-	-	-3.461	0.001	HS
	TN BT-AT	15	8.00	120.00	-	-	-	-	-3.578	0.000	HS
painDETECT	DN BT-AT	15	8.00	120.00	-	-	-	-	-3.420	0.001	HS
	TN BT-AT	15	8.00	120.00	-	-	-	-	-3.436	0.001	HS
Rheumatoid Arthritis Pain Scale	DN BT-AT	15	8.00	120.00	-	-	-	-	-3.417	0.001	HS
	TN BT-AT	15	8.00	120.00	-	-	-	-	-3.408	0.001	HS
SF-36 total score	DN BT-AT	-	-	-	15	8.00	120.00	-	-3.411	0.001	HS
	TN BT-AT	-	-	-	15	8.00	120.00	-	-3.409	0.001	HS

Table no. 5: statistical analysis for observed result for objective parameters.

		PAIRED T TEST					
		DHANYAMLA PARISHEKA			*TWAKA NIRGUNDI PARISHEKA*		
Sl. No	Symptomatic variables	Before treatment (Mean)	After treatment (Mean)	Reduction Percentage	Before treatment (Mean)	After treatment (Mean)	Reduction Percentage
1	Erythrocyte sedimentation rate	59.0667	40.0667	32.1670%	65.7867	40.0667	39.0960%
2	C reactive protiens	18.5733	18.5733	0%	16.5667	16.5667	0%
3	RA factor	81.9733	81.9733	0%	113.9400	113.9400	0%

Table no. 6: Statistical analysis between the group by mann-whitney u test.

Parameter	Treatment	N	Gr-A (n)	Gr-B (n)	Mean rank Gr A	Mean rank Gr B	Sum of rank Gr A	Sum of rank Gr B	U value	Z Value	P Value	Remarks
Sandhishoola	BT-AT	30	15	15	15.83	15.17	237.50	227.50	107.500	-0.222	0.824	NS
Sandhistabdhata	BT-AT	30	15	15	17.70	13.30	265.50	199.50	79.500	-1.699	0.089	NS
ACR Revised Criteria	BT-AT	30	15	15	12.93	18.07	194.00	271.00	74.000	-1.998	0.046	S
Visual Analogue Scale	BT-AT	30	15	15	8.37	22.63	125.50	339.50	5.500	-4.634	0.000	HS
painDETECT	BT-AT	30	15	15	18.30	12.70	274.50	190.50	70.500	-1.770	0.077	HS
Rheumatoid Arthritis Pain Scale	BT-AT	30	15	15	20.33	10.67	305.00	160.00	40.00	-3.016	0.003	S
SF-36 total score	BT-AT	30	15	15	15.00	16.00	225.00	240.00	105.00	-0.312	0.755	NS

Table no. 7: Statistical analysis of objective parameter between the group by Unpaired t-test test.

Parameter	Treatment	Group	N	Differencein mean	Unpaired t-test S. D	Unpaired t-test S.E.M	Unpaired t-test T	Unpaired t-test P	Interpretation
ESR	BT- AT	Group A	15	-19.000	14.056	3.629	1.315	0.199	NS
		Group B	15	-25.720	13.925	3.595			
CRP	BT- AT	Group A	-	-	-	-	-	-	-
		Group B	-	-	-	-	-	-	-
RA	BT- AT	Group A	-	-	-	-	-	-	-
		Group B	-	-	-	-	-	-	-

DISCUSSION

Amavata is characterized by the predominance of *kapha* and *vata doshas*, clinically characterized by the predominance *sandhi soola, sandhi stabdhat, Angamardha, aruchi, trushna, alasya, gourava, jwara, apaka, sandhi shotha* closely aligning with the set of symptoms described for rheumatoid arthritis. Rheumatoid arthritis is understood as a chronic inflammatory disorder, with symptoms often expressed in a *pittotsarga* state. In such cases, *drava sweda* is considered the treatment of choice for *bahirparimarjana chikitsa*, as *shola* is present in *sarvanga* and *drava sweda* is the choice in *pitta samsrishta vyadhi*.

Parisheka sweda is a *shamanang sweda* benefiting patient by reducing stiffness in joints, improving mobility. It also does *mardavta, twaka prasadna, stroto nirmalatwama, nidra and tandra nasha*. Most importantly it does *agnidipti* and increases desire for food. All these factors contribute to normalize the *agni* and relieve *ama*.

Shola in *amavata* is due to *ama* along with *prakupita vata* enters *koshta, trik sandhi* and sandhi.[13]

Dhanyamla parisheka is one of the *rooksha swedana* procedures commonly employed in the treatment of 80 types of *vata rogas* and *vata-pradhana rogas*. It possess *gunas* like *Kapha vatahara, Deepana, pachana, Ruchya, Shulahara which contributes in alleviation of ama and vata.* Additionally, *twak* is recognized for its *kapha-vata shamana* properties and is indicated for *Amavata. Nirgundi*, known for its *vatasleshmahara* properties, also possesses *amavatahara* qualities. Hence this maybe the reason behind the effective result in the study in which all 30 patients showed statistically marked improvement in pain parameter in both *dhanyamla parisheka and twaka nirgundi parisheka.*

CONCLUSION

As per the result, Both *dhanyamla parisheka* and *twaka nirgundi parisheka* stastistically reduced of pain parameters in patients with *Amavata* following treatment. No much statistically significant difference was observed in hematological values either after treatment or after the follow-up period.

When comparing the two groups, showed similar levels of improvement in *Sandhishoola*. However, according to the ACR revised criteria, the Visual Analogue Scale, and the SF-36 total score*, dhanyamla parisheka* exhibited better overall improvement than *twaka nirgundi*

parisheka post-treatment. Conversely*, twaka nirgundi parisheka* showed greater improvement than *dhanyamla parisheka* based on the pain DETECT scale, the Rheumatoid Arthritis Pain Scale, and Erythrocyte Sedimentation Rate (ESR) results. Whereas, no changes were found in RA factor and C reactive protiens after the treatment in both the groups.

Hence, both *dhanyamla parisheka* and *twaka nirgundi parisheka* statistically significant improvement pain parameter and no difference on in between group comparision.

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