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Research Article

A CLINICAL STUDY TO STANDARDIZE THE PROCEDURE OF *DHANYAMLA DHARA* AND TO ASSESS ITS EFFICACY IN RHEUMATOID ARTHRITIS

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ABSTRACT

In this era of globalization and standardization there is a dire need to arrive at a consensus in the approach to the treatment of the diseases in Ayurveda. It is an essential tool not only for proper understanding of the pathology, appropriate diagnosis, and treatment, but also for scientific documentation and generation evidence for global acceptance and appreciation among the scientific community.

Classics clearly demarcate the effects of *Sweda* as an operative and as a pre-operative/post-operative (or both procedures). Considering the therapeutic importance of one such *Swedana* modality, study was attempted on standardization of the procedure of *Dhanyamla dhara*, a form of *Parisheka sweda*.

Based on the references in the classics, the data collected through questionnaires and personal interviews a protocol was developed and it was clinically tested in the disease, Rheumatoid Arthritis. The study was carried out in the Department of Panchakarma, Government Ayurveda College, Tripunithura. Patients diagnosed of Rheumatoid Arthritis (As per American College of Rheumatology revised criteria 1987) under the age group of 16-60 years were selected according to the inclusion criteria and were admitted to the IP Unit. Assessment was done by using clinical parameters (objective and subjective) before treatment and after treatment. The results were statistically analyzed using the most appropriate statistical tests. Significant results were noted in all the clinical parameters such as joint pain, joint swelling, tenderness, general functional capacity signifying the effectiveness of *Dhanyamla dhara* in improving the clinical features and quality of patient's life.

KEYWORDS: *Swedana, Dhanyamla dhara, Parisheka sweda,* Rheumatoid Arthritis.

INTRODUCTION

Ayurveda being a science with a very rich legacy, somewhere lacked to convince the masses. For global acceptance of Ayurveda and related *Panchakarma* therapies - thoroughly conducted researches, standardization of the different therapeutic techniques and hence setting therapeutic standards is needed, so that this unique therapeutic modality may be acknowledged worldwide.

During the course of time, in Ayurveda various therapies have been developed and customized as per the requirement of the present era, which needs standardization, for acceptability by the whole scientific community, and should be practically assessable to the physician and patients without hampering the basic concepts of *Ayurveda.*

One such very less explored theory is that of *Swedana*. *Acharya Charaka* has mentioned *Swedana* under *Shad-upakramas* [1], thus respecting *Swedana* as a principal method of treatment. Diseases of *Vatavaha srotas* as well as *Asthivaha srotas* can be effectively managed with *Dhanyamla* having properties of *Vatanulomana*, *Shula prashamana*, *Nadi uttejaka*, *Vedana sthapana*, *Mastishka balakaraka* and *Sheeta prashamana*[2]. *Vata-rakta* is a typical example of *Avarana Vata*. If we analyze the sign and symptoms of Rheumatoid arthritis and *Vatarakta*, we will be able to understand a very close similarity between the diseases. *Swedana karma* is indicated in *Samaja* and *Kaphadika Vatavyadhis*[3]. *Dhanyamla* is *Vata-kaphahara* and *Amahara*, hence indicated in *Vatasonita* specifically in *Uttana Vatarakta* having symptoms like *Daha, Raga, Kandu* etc. as *Drava sweda* for *Parisheka* [4].

Earlier works carried out

1. Ranasinghe R.L.D.S. under the guidance of Prof Ediriweera E.R.H.S.S, Comparative evaluation of *Dhanyamla Vasti* and *Kayasheka* in the management of *Amavata* w.s.r. to Rheumatoid Arthritis. Department of Nidana Chikitsa, Post graduate Unit, Institute of Indigenous Medicine, University of Colombo.
2. Ollakkod S. under the guidance of Prasad KSR, Evaluation of comparative efficacy of *Alambushadi yoga* and *Dhanyamla Kayasheka* in *Amavata* (Rheumatoid Arthritis), 2004, Department of Kayachikitsa (PG), Post graduate studies and research centre, D.G.M.

Objectives

1) To standardize the procedure of *Dhanyamla dhara*.
2) To assess the efficacy of *Dhanyamla dhara* in reducing signs & symptoms of Rheumatoid Arthritis
3) To know whether the treatment improves the functional capability of Rheumatoid Arthritis patients.

MATERIALS AND METHODS

Study population

The population comprises of 30 patients diagnosed of Rheumatoid Arthritis (RA) as per the inclusion criteria and they were randomly divided into two groups comprising of 15 patients in each group by lottery method. *Dhanyamla* was administered in the form of *Dhara* for 7 days.

Settings of the study

Population: Diagnosed cases of Rheumatoid Arthritis coming under the inclusion criteria.

Sample: The patients (samples) were selected from the OP units of the Dept. of Panchakarma, Govt. Ayurveda College Hospital, Tripunithura. Patients were randomly selected for the study.

Sample frame

a. **Study design:** Randomized interventional comparative clinical trial
b. **Sample size:** 30 (2 groups – 15 patients in each group)
c. **Study duration:** 18 months
d. **Selection of patients:** As per inclusion and exclusion criteria
e. **Study setting:** Govt. Ayurveda College Hospital, Tripunithura, Kerala.

Criteria for Diagnosis

Criteria for diagnosis were as per American College of Rheumatology (ACR)[5], 1987 revised criteria for the classification of Rheumatoid arthritis. Routine haematological, urine, biochemical investigations were carried out to exclude any other pathological condition.

Inclusion criteria

a. Patients diagnosed to have Rheumatoid Arthritis (based on revised ARA criteria for the diagnosis of RA).
b. Patients between 16 – 60 years of age.
c. Patients of both sexes.
d. Patient willing to give written informed consent.

Exclusion criteria

a. *Swedana anarhas*[6]
b. Patients diagnosed with bone disorders like malignancy, Gout, and Bone marrow disorder.
c. Patients below 16 and above 60 years of the age.
d. Patients with complications like deformity, complete loss of functions, patients with cardiac disorders, severe hepatic disorders, endocrinal disorders, pregnant and lactating females.
e. Any other condition that may jeopardize the study.

Drug preparation

Dhanyamla was prepared in the pharmacy of Govt. Ayurveda College Hospital, Tripunithura as per *"Sahasrayogam"* [7] (Figure no. 1) wherein it is mentioned that it can be used in all 80 types of *Vatarogas*.

Drug intervention

Questionnaire (*Purvakarma, Pradhanakarma, Paschatkarma* along with details regarding *Dhanyamla dhara* like quantity, time, amount, pH, positions etc.) was prepared after detailed study of the *Ayurvedic* literature and other authentic available resources about *Dhanyamla dhara*.

Hundred eminent scholars and successful practitioners of *Ayurveda*, inside and outside Kerala were chosen. The prepared questionnaires were distributed through e-mails.

a) Selection of a protocol from the collected data

Based on the references in the classics, the data collected through questionnaires and personal interviews a protocol was developed and it was clinically tested in Rheumatoid Arthritis.

Materials Required

Dhanyamla (3-4 litres/day), Vessels (Two), Soft towels (Three), Oil for *talam*[8] (10 ml), *Rasnadi churna*[10] (5 gm), Gauze (One), Cotton ear plugs (Two), Masseurs (Two), Attendant (One), Thin cloth (1-approx.2m x 1m), *Jambeera*/lemon (half piece).

All these standards were same for both the groups except that thin cloth was required for covering the patient's body in Group B only.

Table no.-1 Showing allocation of patients in two groups

Group A	*Dhanyamla dhara* was done according to practices followed, without covering patient's body and with single stream of *Dhara*. (with the help of *Kindi*)
Group B	*Dhanyamla dhara* done after data collection and making standard protocol. All other parameters were kept same as for group A except that in this group patient's whole body, below the neck area was covered by a thin cloth and multiple stream/*Sahasra dhara* was done.

Procedure of *Dhanyamla dhara* administration

a. *Purvakarma*
b. *Pradhana Karma*
c. *Paschat Karma*

a. *Purvakarma* (Pre-operative procedures)

Patient was made to sit on the *Droni*, *Talam* (specific for each disease) of *Rasnadi choornam* and *Jambeera swarasa*, was kept on the bregma part of the head. Gauze was tied around the head above the eye brows. Ears were plugged with cotton. This protocol was followed for Group-A patients but for Group-B, patient's whole body below the neck was covered with a thin cloth.

b. *Pradhana karma* (Main procedure)

The temperature of *Dhanyamla* was kept around 40°C - 44°C avoiding any discomfort to the patient at that temperature. Warm *Dhanyamla* was poured with *kernels/mugs* (*Kindi*-vernacular Malayalam) in group A patients and by *gardening pitcher* in group B patients, by two attendants standing on either side of the Droni. *Dhara* was done at a medium speed and from a height of 9-12 cm.

Daily fresh *Dhanyamla* was taken. The entire procedure was done in seven positions. *Dhara* was done for 6-7 minutes in each position coming to a total of approximately 42-49 minutes every day. The time duration can be increased or decreased according to the condition and need of the patient and the disease.

c. Paschat karma (Post operative procedure)

After *Dhara*, the body and head was cleaned carefully so that no moisture is retained. Ear plugs, gauze was removed and after wiping well with a dry cloth, *Rasnadi choornam* was applied to the head. *Ghandharvahastadi kashaya* [9] (75 ml) was given to the patient as *Pathy kashaya* [10], a Malayalam vernacular term denoting the post–operative internal medication. The aim of this *Kashaya* is to drain the daily accumulated by products of the body metabolism, owing to augmented permeability by *Swedana*. It helps to maintain the normal order of bodily functions. Rest was advised for about 45 minutes followed by body wash with pleasantly warm water. Then food intake was allowed with the prescribed restrictions. Same procedure of *Dhara* with *Dhanyamla* was done for 7 days.

ASSESSMENT CRITERIA

The assessment was made using clinical parameters. The findings and results were recorded before and after *Dhanyamla dhara*.

1. Pain

Table 2 (A): Quantitative pain assessment: How often is it painful to

		Without difficulty	Some difficulty	Much difficulty	Unable to do	Before Treatment	After Treatment
a)	Dress yourself?	0	1	2	3		
b)	Get in and out of bed?	0	1	2	3		
c)	Lift a cup or glass to your lips?	0	1	2	3		
d)	Walk out doors on flat ground?	0	1	2	3		
e)	Wash and dry your entire body?	0	1	2	3		
f)	Bend down to pick up clothing from the floor?	0	1	2	3		
g)	Turn faucets on or off?	0	1	2	3		
h)	Get in and out of a car / bus etc.?	0	1	2	3		
Total Score							

0-4- Normal; 5-12- Adequate; 13-20- Impaired; 21- 24- Disabled

(B) Visual analogue scale (VAS)

A scale 10 cm was drawn on a paper and the patient was instructed mark against the reading relating to his or her pain severity before and after treatment, which was considered to be the initial pain scale readings. The procedure was done before and after the treatment.

0	-	Nil
1-3	-	Mild
4-6	-	Moderate
7 and above	-	Severe

2. Swelling

Score		Symptom
0	-	No swelling
1	-	slightly obvious
2	-	covers well the bony prominence/ Moderate
3		much elevated so that joints seems grossly deformed/ severe

3. Stiffness

Score		Symptom
0	-	No stiffness
1	-	Stiffness lasting for 30 minutes
2	-	Stiffness lasting up to 60 minutes
3		Stiffness lasting for more than 1 hour

4. Warmth

Score		Symptom
0	-	Normal
1	-	Below
2	-	Raised

5. Tenderness

Score		Symptom
0	-	No tenderness
1	-	Subjective experience of tenderness
2	-	Wincing of face on pressure
3	-	Wincing of face with withdrawal of affected parts on pressure
4	-	Resistance to touch

6. Range of movement: The range of movements was assessed with the help of Goniometer. Ranges of movement before and just after treatments were recorded for both the groups.

The Range of movement was taken as below:

Ankle		Dorsi Flexion, Plantar Flexion
Knee	-	Flexion
Elbow	-	Flexion, Dorsi Flexion
Wrist	-	Plantar Flexion, Abduction
Shoulder	-	Flexion, Extension

Here assessment is based on the degree of movements.

7. General Functional Capacity

Score		Symptom
0	-	Complete ability to carry or all routine duties without handicap
1	-	Frequent normal activity despite slight difficulty in joint movements
2	-	Few activities are persisting but patient can take care of him/herself
3		Few activities are persisting, patient requires an attendant to take care of him/herself
4		Patient is totally bed ridden

8. Walking time: Patients were asked to walk a distance of 40 feet and the time taken was recorded before and after the treatment.

Score		Walking time (in secs)
0	-	30-40
1	-	41 – 50
2	-	51 – 60
3		More than 60

9. Grip strength: To find the functional capacity of affected upper limb, the patient's ability to compress an inflated ordinary sphygmomanometer cuff under standard condition was carried out and the findings were recorded before and after treatment.

Grip strength score		Pressure in sphygmomanometer
0	-	200 mm Hg or more
1	-	198 – 200 mm Hg
2	-	118 – 70 mm Hg
3		Under 70 mm Hg

Laboratory Parameters used for assessment

1. RA factor

2. Estimation of Acute phase reactants

a) Erythrocyte Sedimentation Rate (ESR)

b) C - reactive protein (CRP).

Score

0 Negative (less than 6 IU)

1 Positive (more than 6 IU)

RESULTS AND DISCUSSION

Criteria for the Assessment of the total effect of the therapy

The subjective and objective criteria were assessed before and after treatment. The data obtained in clinical study was subjected to following two statistical tests (for parametric/non-parametric data) and was analyzed accordingly;

1. The Wilcoxon signed rank test

2. Student paired't' test

1. Pain

Table 3: Showing effect of therapy as per (a) Quantitative pain assessment

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0 - 4	2	2	2	3
5 - 12	4	4	3	6
13 -20	6	9	8	6
21 - 24	3	0	2	0
Total	15	15	15	15

	Mean		Z-value	p-value
	BT	**AT**		
Group A	14.533	12.2	-3.192	.0008
Group B	14	11.067	-3.351	.0002

BT-Before treatment At- After treatment

The statistical analysis of the quantitative pain assessment showed extremely significant results in both the groups after treatment. There was gradual reduction of pain in patients of both the groups. Gradual improvement in joint movements was seen due to reduced pain. The results were more significant in group B (Z-value – 3.192), as compared to group A (Z-value - 3.351). So *Dhanyamla dhara* is very effective in reducing the pain.

Table 4: Showing effect of therapy on (b) Visual analogue scale for pain

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	0	0	0	0
1 – 3	0	11	0	12
4 – 6	2	4	4	3
7 & above	13	0	11	0
Total	15	15	15	15

	Mean		Z value	p value
	BT	**AT**		
Group A	7.466	3.266	-3.443	.0005
Group B	7.2	3.066	-3.496	.0004

Analysis of Visual Analog Scale (VAS) to assess pain showed a highly significant reduction in pain after treatment. Z-values for both the groups showed that it was more significant for group B than group A.

2. Swelling

Table 5: Showing effect of therapy on Swelling in joints

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	0	0	1	3
1	0	9	4	7
2	8	6	8	5
3	7	0	2	0
Total	15	15	15	15

	Mean		Z value	p value
	BT	**AT**		
Group A	2.466	1.6	-3.606	.003
Group B	1.733	1.133	-2.714	.006

The mean changes, hence the reduction of joint swelling is statistically significant in both the groups after treatment. Because of the reduction in swelling, the range of movement of the major joints was increased. The results were more significant in group A at p-value .003 than in group B at p value .006. But overall *Dhanyamla dhara* is found to be very effective in reducing the swelling.

3. Stiffness

Table 6: Showing effect of therapy on Stiffness

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	0	2	0	1
1	3	5	3	5
2	6	7	6	9
3	6	1	6	0
Total	15	15	15	15
	Mean		**Z value**	**p value**
	BT	**AT**		
Group A	2.2	1.467	-2.810	.005
Group B	2.2	1.533	-2.887	.004

In both categories of patients, the analysis showed significant results after treatment, due to the reduction of stiffness of muscles and joints, the subjects from both the groups were able to walk without or with minimal support. For most of the patients, duration of morning stiffness was reduced otherwise. So the therapy was effective in reducing the stiffness.

4. Warmth

Table 7: Showing effect of therapy on Warmth

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	5	11	4	12
1	2	2	3	2
2	8	2	8	1
Total	15	15	15	15
	Mean		**Z value**	**p value**
	BT	**AT**		
Group A	1.2	.4	-2.449	.014
Group B	1.2667	.2667	-2.714	.006

The mean changes, before and after treatment were significant statistically in group A and highly significant in group B. This might be because of the anti-inflammatory effect of *Dhanyamla*

5. Tenderness

Table 8: Showing effect of therapy on Tenderness – Group A

		Mean		Z value	p value
		BT	**AT**		
Ankle jt. Rt.	Group A	3	1.33	-3.494	.0004
	Group B	3.067	1.133	-3.771	.0001
Ankle jt. Left	Group A	3	1.2	-3.535	.0004
	Group B	3.066	1.133	-3.771	.0001
Knee jt. Right	Group A	3.066	1.266	-3.626	.0002
	Group B	3.133	1.4	-3.557	.0003
Knee jt. Left	Group A	3.067	1.333	-3.578	.0003
	Group B	3.133	1.4	-3.557	.0003
Elbow jt. Right	Group A	3.066	1.333	-3.557	.0003
	Group B	3.2	1.533	-3.494	.0004
Elbow jt. Left	Group A	3	1.2	-3.354	.0007
	Group B	3.2	1.466	-3.578	.0003
Wrist jt. Right	Group A	2.667	1.133	-3.416	.0006
	Group B	2.733	1.133	-3.52	.0004
Wrist jt. Right	Group A	2.666	1.2	-3.314	.0009
	Group B	2.733	1.2	-3.416	.0006

In both categories of patients, the analysis showed extremely significant results after treatment at $p < .001$ level. Due to the reduction of tenderness of joints, subjects from both the groups were able do their work themselves.

6. General Functional Capacity

Table 9: Showing the effect of therapy on General functional capacity

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	0	0	0	2
1	2	4	3	3
2	7	6	4	3
3	5	4	5	4
4	1	1	3	3
Total	15	15	15	15
	Mean		**Z value**	**p value**
	BT	**AT**		
Group A	2.333	2.133	-1.732	.0832
Group B	2.6	2.2	-2.449	.0143

The mean changes, before and after treatment is insignificant statistically in group A, whereas found to be significant in group B. The patients of Group B were able to take care of themselves and do work with slight joint pains and deformities.

7. Walking Time (in seconds)

Table 10: Showing effect of therapy on walking time

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	1	2	3	5
1	5	11	6	9
2	6	2	5	1
3	3	0	1	0
Total	15	15	15	15
	Mean			
	BT	**AT**	**Z value**	**p value**
Group A	1.733	1	-2.81	.0049
Group B	1.2667	.733	-2.82	.0046

The mean score of walking time in both the Groups reduced after treatment. The mean changes, before and after treatment were significant statistically in group A and B, but Z-value shows it to be more significant in group B than A. There were significant results in the walking time in patients of both the groups due to reduction of inflammatory changes in the joints. This indicates that there is increase in functional capability of subjects due to treatment.

8. Grip Strength

Table 11: Showing effect of therapy on grip strength

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	1	3	2	6
1	6	10	4	7
2	5	2	6	2
3	3	0	3	0
	Mean			
	BT	**AT**	**Z value**	**p value**
Group A	1.733	.933	-2.972	.0029
Group B	1.66	.733	-2.889	.0038

Grip power was found to be statistically highly significant after treatment in both the groups with p-value .003. This improvement shows that the power of the joint was increased due to treatment and showed good results in the minor joints that were affected.

9. Rheumatoid Arthritis (RA) Factor

Table 12: Showing effect of therapy on RA factor

	Mean		Z value	p value
	Before Treatment	After Treatment		
Group A	1.2	1.2	0	1
Group B	1.066	1.333	1	.317

Table 13: Showing effect of therapy on RA factor (Quantitatively)

	N	Mean		S.D. BT	S.D. AT	t value	p value
		BT	AT				
Group A	15	158.21	140.11	52.821	52.74	3.114	.008
Group B	15	188.79	119.55	69.372	55.647	6.581	.000

The mean changes, before and after treatment were insignificant statistically in both the groups.

At the same time when paired sample 't' was applied for the parametric data of RA factor then the results were found to be statistically highly significant in both the groups after treatment. This analysis shows that there was remarkable decrease in the values of RA factor after therapy, hence improvement in the immunological changes taking place in the body.

10. Erythrocyte Sedimentation Rate (ESR)

Table 14: Showing effect of therapy on ESR

	N	Mean		S.D. BT	S.D. AT	t value	p value
		BT	AT				
Group A	15	67.06	25.867	24.010	7.846	8.445	.0001
Group B	15	59.6	28.800	30.757	20.685	4.413	.0010

There were significant results statistically in the reduction of ESR after treatment in both the groups. The reduction in ESR represents reduced inflammation of joint and joint capsule which improved the quality of life of patients in both the groups. This reduction is highly impressive due to the relief of disease process.

11. C – Reactive Protein

Table 15: Showing effect of therapy on C-reactive protein

	Group A		Group B	
Scores	**BT**	**AT**	**BT**	**AT**
0	2	13	2	13
1	13	2	13	2
Total	15	15	15	15
	Mean		**Z value**	**p value**
	BT	**AT**		
Group A	.8667	.1333	3.317	.0009
Group B	.8667	.1333	3.317	.0009

The mean score of CRP values in both the groups before treatment and after treatment were extremely significant statistically at p<.001. This indicates that *Dhanyamla* remarkably reduced the inflammatory changes and hence decrease in signs and symptoms of inflammation in both the groups.

DISCUSSION

Vatarakta is considered as *Avaranjanya vata vyadhi*. *Acharya Charaka* [11] and *Vagbhata* [12] have advised therapies that are *Anabhisyandi*, *Snigdha* and which help in the cleansing of the channels of circulation (*Srotoshodhana*). If ailment is caused by the aggravated *Vayu* occluded by *Pitta* then, the patient should be specially given heating and cooling therapies alternatively **[13]**.

"*Ushnaveeryo himasparshi*"**[14]** is property of *Amla rasa* which is also manifested in *Dhanyamla* as it is *Sheeta* (cold) at *Sparsha* (perception) which alleviates *Rakta* by its nature and *Ushna* in *Guna* and *Veerya* (potency) which alleviates *Vata*, hence is ideal for external administration in *Rakta-avarita vata.* Hence *Dhanyamla* by virtue of its *Amla rasa* and *Ushna veerya* not only does *Srotoshodhana* and alleviation of *Vata* and *Rakta* but also does *Anulomana* of *Vata.* Hence it has got all the desirable properties to be used in *Rakta-avarita vata.* As per the assessment criteria *Dhanyamla dhara* was found to be statistically and clinically effective in all the parameters (viz. pain, stiffness, warmth, Range of motion etc.) taken for assessment.

CONCLUSION

The standardized procedure adopted in Group B was found more effective and beneficial, without any complications, in comparison to the method adopted for Group A. Minor complications (as observed in Group A) like chills and rigors, arising during *Dhanyamla dhara* may happen due to uneven maintenance of temperature of *Dhanyamla* or prolonged time gap between the changing up of fresh warm *Dhanyamla* or if body is exposed to cold breeze, which can be simply avoided by doing *Dhara* after covering the patient's body with a thin cloth, as it will help in maintaining the body temperature throughout the procedure.

Treatment responses were highly significant in most of the parameters assessed which clearly implies that *Dhanyamla dhara* remarkably reduces the signs & symptoms of RA, especially Acute or Acute-on-chronic cases and can relieve intense pain, reduce swelling and improves functional capacity within 7 days.

So it can be concluded that *Dhanyamla dhara* can be incorporated as a safe & effective part of treatment protocol for the management of *Vatarakta* having acute signs and symptoms as mentioned by the *Acharyas*.

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