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STUDY TO EVALUATE THE EFFICACY OF *KALA VASTI* [*RASNADASHMOOLAKAM* AND *SAINDHVADYA TAILA BRHAT*] IN *AMAVATA* (RHEUMATOID ARTHRITIS)

Dr. Alka Narnolia*[1] and Prof. (Dr.) N. R. Singh[2]

[1]MD Scholar, PG Department of Kaya Chikitsa, Ch. Brahm Prakash Ayurved Charak Sansthan, New Delhi.

[2]Prof. HOD, PG Department of Kaya Chikitsa, Ch. Brahm Prakash Ayurved Charak Sansthan, New Delhi.

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***Corresponding Author**
Dr. Alka Narnolia
MD Scholar, PG Department of Kaya Chikitsa, Ch. Brahm Prakash Ayurved Charak Sansthan, New Delhi.

ABSTRACT

Introduction: *Amavata* was firstly described by *Madhavakara* in 700AD and mentioned that *Ama* and *Vata* plays a vital role in the pathogenesis of this disease. *Ama* is caused due to derangement of *Agni* especially *Jatharagni*. It is initiated by the consumption of *Virudha Ahara* (incompatible food) in the pre-existence of *Mandagni*. In it vitiated *Vayu* forcefully circulates the *Ama* all over the body through *Dhamnies* (circulatory channels) which take shelter in the *Sleshma sthana* [*Amashyas*, *Sandhi* etc.] producing symptoms of *Amavata*. Rheumatoid Arthritis is a chronic inflammatory disease of unknown aetiology marked by a symmetric, peripheral polyarthritis, often result in joint damage and physical disability. Serum antibodies to cyclic citrullinated peptide (Anti-CCPs) are routinely used along with Rheumatoid factor as a bio marker of diagnostic and prognostic significance. About 0.8% (0.3% to 2.1%) of the population worldwide is affected by this disease. In India the prevalence of this disease is 0.5% to 0.75%. Mostly the middle age group persons are affected. **Aim and Objective: Aim-** To evaluate the efficacy of *Kala Vasti (Rasnadashmoolakam* and *Saindhvadya Taila Brhat*) in the management of *Amavata* (Rheumatoid Arthritis). **Objective-** Reduction of Subjective parameters, Objective parameters and Biochemical parameters of *Amavata* (Rheumatoid Arthritis). **Material and Methods:** A total of 48 patients were registered according to inclusion and exclusion criteria and randomly (by chit lottery method) divided into two groups from *Kayachikitsa* OPD / IPD of CBPACS, New Delhi and 40 patients were

completed the trial. Group-A will be administered *Kala Vasti* (*Niruha Vasti* with *Rasnadashmoolakam* and *Anuvasana* with *Saidhvadya Taila Brhat*). Group-B will be administered (*Niruha Vasti- Vaitarana Vasti* and *Anuvasana* with *Saidhvadya Taila Brhat*) as per *Kala Vasti* schedule. **Observation and Result:** In Group A, showed highly significant results $p<0.001$ in *Jwara*, *Sandhiruja*, *Sandhisotha,* Ritchie Articular index (RAI), DAS 28 criteria, VAS (Visual Analogue Scale), Walking time, ESR, CRP and in *Stabdhta*, *Gaurava,* grip strength, RA factor was significant result $p<0.05$. In Group B, showed highly significant result $p<0.001$ in *Stabdhta*, *Gaurava*, *Sandhiruja*, *Sandhisotha*, RAI (Ritchie Articular index), DAS 28 criteria, grip strength, VAS (Visual Analogue Scale), ESR, RA factor and in *Jwara,* Walking Time, CRP was significant result $p<0.05$. There were no adverse effects or complications found after completing the therapy. **Conclusion**: Administration of *Kala Vasti-Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam and Vaitarana Vasti* is a safe and effective medication for *Amavata*.

KEYWORDS: *Ama, Vata, Amavata,* Rheumatoid arthritis, *Kala Vasti, Rasnadashmoolakam.*

INTRODUCTION

Amavata was described for the first time by *Madhavkara* in 700 AD as a separate disease entity and has also mentioned that *Ama* and *Vata* plays a vital role in the pathogenesis of this disease. *Amavata* is one of the most crippling disorder affecting day to day activities of the patients. It not only affects the joints but also affect the whole body. It is named after it's chief pathogenic constituents *Ama* and *Vata*.[1] The main causative factor *Ama* is caused due to derangement of *Agni* especially *Jatharagni*.[2] This disease is initiated by the consumption of *Virudha Ahara* (incompatible food) in the pre-existence of *Mandagni*. In it vitiated *Vayu* forcefully circulates the *Ama* all over the body through *Dhamnies* (circulatory channels) which take shelter in the *Sleshma sthana* [*Amashyas*, *Sandhi* etc.[3] producing symptoms such as stiffness, body ache, anorexia, polydipsia, lassitude, heaviness of body, fever, indigestion of food, swelling on the body.[4] In the later stage pain may begin to migrate from place to place with a *Vrishchika Damshvat Vedana* (intense stinging type of pain) and burning sensation.

Rheumatoid Arthritis which is a chronic inflammatory disease of unknown aetiology marked by a symmetric, peripheral polyarthritis. It is the most common form of chronic inflammatory arthritis and often result in joint damage and physical disability. Because it is a systemic

disease, Rheumatoid Arthritis may result in a variety of extra articular manifestation including fatigue, subcutaneous nodule, lung involvement, pericarditis, peripheral neuropathy, vasculitis and haematological abnormalities. Rheumatoid Arthritis affects the synovial tissue and underlying cartilage and bone. The synovial membrane, which covers most articular surfaces, tendon sheaths and bursae, normally is a thin layer of connective tissue. Serum antibodies to cyclic citrullinated peptide (Anti-CCPs) are routinely used along with Rheumatoid factor as a bio marker of diagnostic and prognostic significance.

The principle of treatment of *Amavata*[5] are *Langhana*, *Swedana* and drug having *Tikta*, *Katu Rasa*, *Deepana*, *Virechana*, *Snehapana* and *Vasti* properties.

Present Status of the Problem

It is a most crippling disease in the present era. About 0.8% (0.3% to 2.1%) of the population worldwide is affected by this disease. In India the prevalence of this disease is 0.5% to 0.75%. Mostly the middle age group persons are affected by this disease. The onset of disease is frequent during 4th and 5th decade of life with 80% of patient developing the disease between 30 to 50 years of age.[6] Community prevalence study shows that female are more suffering than male and the ratio of occurrence between them is 3:1.[7] The world economy is badly affected due to this disease as it affects mostly young person making them crippled and patients become unable to do their job and day to day activities for which they have to depend on other family members. The life of the patients become so much difficult that patients sometimes do not like to survive more.

Lacunae in existing knowledge

In Contemporary system of Medicine, a lot of research work is going on to develop protocol for the management of Rheumatoid Arthritis. Presently NSAIDs, Glucocorticoids, DMARDs are used for treatment for this disease. These medicine have a lot of toxic effect such as Corticosteroids which are used for reducing pain and inflammation of the joint cause osteoporosis, hypertension, diabetes etc. Methotrexate and other DMARDs causes hepatotoxicity, interstitial pneumonitis, nausea and diarrhoea. NSAIDs causes gastritis, peptic ulcer, impairment of renal function.[8]

In Indian System of Medicine, a lot of drugs have prescribed to treat *Amavata* such as *Simhanada Guggulu*, *Yograj Guggulu* etc. Along with these oral medications *Panchakarma*

procedures are also prescribed for treatment of this disease. By the present treatment patients get some relief but till date no satisfactory solution of this disease has been established.

AIM AND OBJECTIVE

Aim- To evaluate the efficacy of *Kala Vasti (Rasnadashmoolakam* and *Saindhvadya Taila Brhat*) in the management of *Amavata* (Rheumatoid Arthritis).

Objective: Reduction of Subjective parameters, Objective parameters and Biochemical parameters of *Amavata* (Rheumatoid Arthritis).

In this study *Rasnadashmoolakam Kwatha*[9] and *Saindhvadya Taila Brhat*[10] had been administered to the patients in the form of *Kala Vasti* course. *Rasnadashmoolakam Kwatha* as described by *Acharya Chakrapani Datta* in his famous compendium *Chakradatta* in chapter no. 25/5 contains *Dashmoola, Amrita, Eranda, Rasna, Shunthi* and *Devdaru* as ingredients. Most of these drugs have *Vata* pacifying, *Srotoshodhaka* (channel cleansing) property and have stimulating effect on digestive and metabolic functions. *Saindhvadya Taila Brhat* as described by *Govind Das* in *Bhaishajya Ratnavali* contains *Saindhava Lavana, Sreyasi, Rasna, Satapuspa, Yamanika, Sarjika, Maricha, Kustha, Shunthi, Sauvarcala, Vida, Vaca, Ajamoda, Madhuka, Jiraka, Pauskara, Pippali, Eranda taila*.

'Vaitarana Vasti[11]*'* was selected as 2nd trial intervention mentioned in *Chakradatta in Niruhadhikara* 73/32. Ingredients of *Vaitarana Vasti* are *Amalika (Emali), Guda, Saindhava, Gomutra* and *Tila taila.* As a whole, the qualities of *Vaitarana Vasti* can be considered as *Laghu, Ruksha, Ushna, Tikshna*. Both the trial drugs have *Deepana, Pachana, Vatakaphashamaka, Vedanasthapana, Shothahara* properties. Its contents are found to possess analgesic, anti-inflammatory and anti-oxidant properties.

MATERIAL AND METHODS

Research Design

- Study type- Open label observational / interventional, Efficacy study.
- Study design
  - Level of study : OPD/IPD
  - Timing : Prospective
  - No. of groups : Two (Group A and Group B)
  - Groups allocation : Random (Lottery method)
  - Study centres : Single centred

CBPACS, Khera Dabar, New Delhi

- Duration of study : 18 months

Ethical Clearance and Ctri Registration

This study was approved by Institutional Ethical Committee (IEC) of Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, New Delhi, vide letter no. 2017/01/MD/17; dated 28.09.2017 and also registered in Clinical Trial Registry of India (CTRI; www.ctri.nic.in) vide Registration No: CTRI/2018/07/015081, dated 26-07-2018 before starting the clinical trial on clinically diagnosed patients of *Amavata.*

Inclusion Criteria

1. Cases will be selected randomly regardless of sex, occupation and socioeconomic status.
2. The patients between the age group of 21 to 50 years.
3. Patient suffering from disease since at least 3 years.
4. *Amavata* will be diagnosed according to the clinical features as described in *Madhava Nidana (Ma.Ni.25/6-10).*
5. The patients should fulfil the 2010 ACR-EULAR criteria for Rheumatoid Arthritis.

Exclusion Criteria

1. Patients having severe crippling bone deformities.
2. Patients suffering from paralysis.
3. Patients having any type of Arthropathy such as neoplasm of spine, Gout, Ankylosing spondylitis, Traumatic arthritis and pyogenic osteomyelitis etc.
4. Patients having associated Cardiac disease, Tuberculosis, malignant hypertension, Impairment of Liver functions, Impairment of Renal functions, malignancy, HIV-AIDS etc.
5. Pregnant women and lactating mother.

Withdrawal Criteria

1. Patient not willing to continue treatment.
2. Patient develops any life threatening adverse effect during this trial.
3. If patient develops any acute illness during the trial which may hamper the study.

Hypothesis

Null hypothesis (H_0)- There is no significant difference between the efficacy and safety of *Kala Vasti* (*Rasnadashmoolakam* and *Saindhvadya taila Brhat*) and *Vaitaran Vasti*.

Alternate hypothesis (H_1)- Whether, significant improvement in efficacy is found by the use of *Kala Vasti* (*Rasnadashmoolakam* and *Saindhvadya taila Brhat*) in *Amavata* (Rheumatoid Arthritis).

A total of 65 people were assesses for eligibility; among them 17 were excluded as they were not meeting the criteria of inclusion. Total 48 subjects were put to randomization. In group A, 23 were allocated for intervention and in group B, it was 25. Excluding the dropouts, a total of 40 completed the follow-up and the data was analyzed statistically.

Drug Preparation and Administration

- **GROUP A:** 20 patients will be given *Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam* in the form of *Kala Vasti* course.

Anuvasana Vasti- Saindhvadya Taila Brhat-60ml.

Niruha Vasti- Rasnadashmoolakam -480ml

Madhu- 60ml

Saindhava- 10gms

Taila- 120ml

Kwatha- 250ml

Kalka- 40gm

Dose Rationale- Sushruta chikitsa sthan.38/40-41

- **GROUP B:** 20 patients will be given *Vaitaran Vasti* in the form of Kala Vasti.

Anuvasana Vasti- Saindhvadya Taila Brhat-60ml.

Vaitaran Vasti-

Saindhava -10gms.

Guda- 20ml

Chincha- 40ml.

Gomutra- 160ml.

Tila Taila- 50ml.

Table No. 01: Intervention Schedule in both the Groups.

	GROUP A (Trial group)	GROUP B
Kala Vasti	A- *Saindhvadya Taila Brhat* N-*Rasnadashmoolakam*	A-*Saindhvadya Taila Brhat* N-*Vaitaran Vasti*
Sample size	20	20
Dose	*Anuvasana*- 60ml *Niruha*- 480ml	*Anuvasana*- 60ml *Vaitaran*- 280ml
Time of Administration	*Anuvasana Vasti* after the consumed light food. *Niruha Vasti* empty stomach.	*Anuvasana Vasti* after the consumed light food. *Vaitaran vasti* empty stomach.
Duration of intervention	16 days	16 days
Follow up	32 days	32 days

Collection of Data

The case history of every patient was recorded as per the Performa designed. The patients were assessed using both subjective and objective parameters as well as laboratory investigations.

Subjective Parameters

1. *Stabdha* (stiffness)
2. *Gaurava* (heaviness of body)
3. *Jwara* (fever)
4. *Sandhiruja* (pain in joints)
5. *Sandhishotha* (swelling)

Objective Parameters

1. DAS criteria (DAS28)
2. Ritchie Articular index
3. Grip strength (mm Hg)
4. Visual Analogue Scale
5. Walking time (40ft.)

Laboratory Investigations

1. ESR
2. R.A. Factor
3. CRP

Follow up

Dates for visit and schedule for follow up was issued to the patients. A follow up was done after 32 days of treatment.

Results with comparison of before and after treatment have been illustrated by using IBM-SPSS software and to access the efficacy of intragroup Wilcoxon Matched Pairs Signed Ranks Test has been used for subjective parameters and Paired T test has been used for objective parameters and laboratory investigations. To access the efficacy of two groups i.e. intergroup comparison Mann Whitney U test for non-parametric data and Unpaired T test for parametric data have been used. Effect of assessment parameters is described in the form of % improvement. The obtained results and its statistical analysis have been given in the form of tables and graphs.

Table no.02: - Plan of Study.

Interventions	Day 0	Day 1	Day 16	Day 48
Screening	√			
Physical examination		√		√
Subjective parameters		√	√	√
DAS-28 Criteria		√	√	√
Ritchie Articular index		√	√	√
Grip strength		√	√	√
Visual Analogue Scale		√	√	√
Walking time		√	√	√
ESR		√	√	√
RA factor		√	√	√
CRP		√	√	√
Kala Vasti		√		

1. OBSERVATIONS AND RESULTS

Table No. 03: General status of clinical trial.

Compliance	Group A	Group B	Total	
			N	%
Registered	23	25	48	100%
Completed	20	20	40	83.33%
Drop-outs	03	05	08	16.66%

OBSERVATION

The highest incidence of *Amavata* was seen in age group of 41-50 years, in which 24 patients (60%), 10 patients (25%) from 31-40 years of age group, 06 patients (15%) from 21-30 years of age group. This shows that incidence of *Amavata* occurring more in middle age. Incidence

of disease is found notably 31 patients (77.5%) were females and 09 patients (22.5%) were males. The majority of the patients were Hindu i.e. 39 patients (97.5%); 30 patients (75%) belongs to urban area and 10 patients (25%) belongs to rural area; the majority i.e.28 patients (70%), belonged to middle class, 07 patients (17.5%) were from poor class and 05 patients (12.5%) were from upper class; maximum 35% of patients were graduates followed by 17.5% high school educated. 22 patients (55%) were having the habit of taking mixed diet; 18 patients (45%) had positive family history, while 22 patients (55%) had no family history; Maximum i.e. 24 patients (60%) were found to be addicted to tea, tobacco, alcohol etc. 23 patients (57.5%) with *Kroora Koshtha* whereas*;* maximum 24 patients (60%) were of *Mandagni*. Maximum 23 patients (57.50%) were of *Vata-Kaphaj Prakriti* which is highly associated with the development of *Amavata;* 27 patients (67.5%) were of *madhyama Sara;* 31 patients (77.5%) had *madhyama* type of *samhanana;* 26 patients (65%) with *Madhyama Satva*; 27 patients (67.5%) had *madhyama satmya*; 28 patients (70%) had *Madhyama ahara Shakti*; 27 patients (67.5%) had *Avara Vyayama Shakti*; 33 patients (82.5%) had gradual onset; 97.5% patients were had metacarpophalangeal joint involvement, 92.5% proximal interphalangeal joint of hand, wrist and knee joint; 30% patients had CRP and 70% patients had RA factor positive before the treatment.

RESULT

The statistical tests were applied with the following assumptions

Hypothesized mean/ median difference = 0.

Level of significance (α) = 0.05.

Confidence interval (CI) = 95%.

In- significant = P value > 0.05.

Significant = P value < 0.05.

Highly significant = P value < 0.001.

Table No. 04: Showing effect on *Stabdhta* of both group patients. (Wilcoxon matched-pairs signed-ranks test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	2.05	1.50	2.00	1.3
Median	2	1	2	1
% of change	26.80%↓		35%↓	
SD	0.759	0.513	0.725	0.6569
SE	0.1698	0.1147	0.1622	0.1469
z value	2.9341		3.2958	
p value	(=0.001)		(<0.001)	
Remarks	Statistically significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In-Significant)

Table No. 05: Showing effect on *Gaurava* of both group patients. (Wilcoxon matched-pairs signed-ranks test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	1.30	0.9	1.25	0.50
Median	1.5	0	1	1
% of change	30.77%↓		60%↓	
SD	0.9234	0.6407	0.7164	0.5130
SE	0.20647	0.1433	0.16018	0.1147
Z value	2.5205		3.4078	
p value	(<0.05)		(<0.001)	
Remarks	Statistically significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 06: Showing effect on *Jwara* of both group patients. (Wilcoxon matched-pairs signed-ranks test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	1.55	0.75	1.70	1.2
Median	2	1	2	1
% of change	51.61%↓		29.41%↓	
SD	0.510	0.5501	0.470	0.4104
SE	0.11413	0.1230	0.10513	0.09177
z value	3.5162		2.8031	
p value	(<0.001)		(<0.05)	
Remarks	Statistically highly significant		Statistically significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 07: Showing effect on *Sandhiruja* of both group patients. (Wilcoxon matched-pairs signed-ranks test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	3.1	2.15	3.70	2.70
Median	3.00	2.00	4	2
% of change	30.65%↓		27.03%↓	
SD	0.788	0.8751	0.4702	0.4702
SE	0.17622	0.1957	0.10513	0.1051
z value	3.823		3.9199	
p value	(<0.001)		(<0.001)	
Remarks	Statistically highly significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 08: Showing effect on *Sandhishotha* of both group patients. (Wilcoxon matched-pairs signed-ranks test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	3.15	2.35	3.05	2.05
Median	3.00	2.00	3.00	2.00
% of change	25.40%↓		32.79%↓	
SD	0.74516	0.7452	0.2236	0.2236
SE	0.16662	0.1666	0.05	0.05
z value	3.5162		3.9199	
p value	(<0.001)		(<0.001)	
Remarks	Statistically highly significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 09: Showing effect on Ritchie Articular index of both group patients. (Wilcoxon matched-pairs signed-ranks test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	2.60	1.75	2.75	1.80
Median	3	2	3	2
% of change	32.69%↓		34.55%↓	
SD	0.503	0.4443	0.444	0.4104
SE	0.11239	0.09934	0.09934	0.09177
z value	3.6214		3.823	
p value	(<0.001)		(<0.001)	
Remarks	Statistically highly significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 10: - Showing effect on DAS criteria (DAS28) of both group patients. (Paired t-test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	6.048	5.216	6.2390	5.549
Mean Difference	0.8325		0.690	
% of change	13.76%↓		11.06%↓	
SD	0.63274	0.680	0.44627	0.5683
SE	0.1415	0.1520	0.09979	0.1271
t value	12.345		9.90	
p value	(<0.001)		(<0.001)	
Remarks	Statistically highly significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 11: Showing effect on Grip strength (mm Hg) of both group patients. (Paired t-test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	0.65	0.45	0.90	0.40
Mean Difference	0.20		0.50	
% of change	30.77%↓		55.55%↓	
SD	0.4894	0.5104	0.5525	0.5026
SE	0.1094	0.1141	0.1235	0.1124
t value	2.179		4.359	
p value	(<0.05)		(<0.001)	
Remarks	Statistically significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 12: Showing effect on Visual Analogue Scale of both group patients. (Paired t-test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	7.15	5.0	7.60	5.750
Mean Difference	2.15		1.85	
% of change	30.07%↓		24.34%↓	
SD	2.033	1.589	1.142	1.070
SE	0.455	0.3554	0.255	0.2392
t value	11.831		14.091	
p value	(<0.001)		(<0.001)	
Remarks	Statistically highly significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 13: Showing effect on Walking time (40ft.) of both group patients. (Paired t-test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	1.5	0.95	1.0	0.65
Mean Difference	0.55		0.35	
% of change	36.66%↓		35%↓	
SD	0.513	0.2236	0.6489	0.5871
SE	0.115	0.050	0.1451	0.1313
t value	4.819		3.199	
p value	(<0.001)		(<0.05)	
Remarks	Statistically highly significant		Statistically significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 14: Showing effect on ESR of both group patients. (Paired t-test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	38.30	32.2	38.95	33.55
Mean Difference	6.10		5.4	
% of change	15.93%↓		13.86%↓	
SD	19.868	16.634	21.395	18.234
SE	4.443	3.720	4.784	4.077
t value	7.266		6.090	
p value	(<0.001)		(<0.001)	
Remarks	Statistically highly significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 15: Showing effect on CRP of both group patients. (Paired t-test).

	Group A		Group B	
	BT	**AT**	**BT**	**AT**
Mean	6.7150	6.33	17.7085	16.120
Mean Difference	0.3850		1.589	
% of change	5.73%↓		8.97%↓	
SD	3.30758	3.179	16.94236	15.373
SE	0.73960	0.7109	3.78843	3.437
t value	5.966		3.827	
p value	(<0.001)		(<0.05)	
Remarks	Statistically highly significant		Statistically significant	

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 16: Showing effect on RA Factor of both group patients. (Paired t-test).

	Group A		Group B	
	BT	AT	BT	AT
Mean	140.7215	132.06	78.5770	72.738
Mean Difference	8.666		5.839	
% of change	6.15%↓		7.43%↓	
SD	249.31169	237.92	78.37071	76.355
SE	55.74779	53.20	17.52422	17.074
t value	3.186		5.572	
p value	(<0.05)		(<0.001)	
Remarks	Statistically significant		Statistically highly significant	

(HS: Highly Significant S: Significant IS: In Significant)

INTER GROUP COMPARISON

Table No. 17: Showing comparative effect on Nonparametric parameters of both group patients. (Mann-Whitney U Test).

Variable	Groups	Mean	SD	SE	Median	z value	P	S
Stabdhta	A	1.5	0.513	0.1147	1.5	0.7979	0.3676	IS
	B	1.3	0.6569	0.1469	1			
Gaurava	A	0.9	0.6407	0.1433	1	1.7447	0.048	S
	B	0.5	0.5130	0.1147	0.5			
Jwara	A	0.75	0.5501	0.1230	1	2.0963	0.0075	S
	B	1.2	0.4104	0.09177	1			
Sandhiruja	A	2.15	0.8751	0.1957	2	2.0963	0.0215	S
	B	2.70	0.4702	0.1051	3			
Sandhisotha	A	2.35	0.7452	0.1666	2	1.3795	0.07	IS
	B	2.05	0.2236	0.050	2			
RAI	A	1.75	0.4443	0.09934	2	0.2569	0.7225	IS
	B	1.80	0.4104	0.09177	2			

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 18: Showing comparative effect on Parametric parameters of both group patients. (Un Paired t-test).

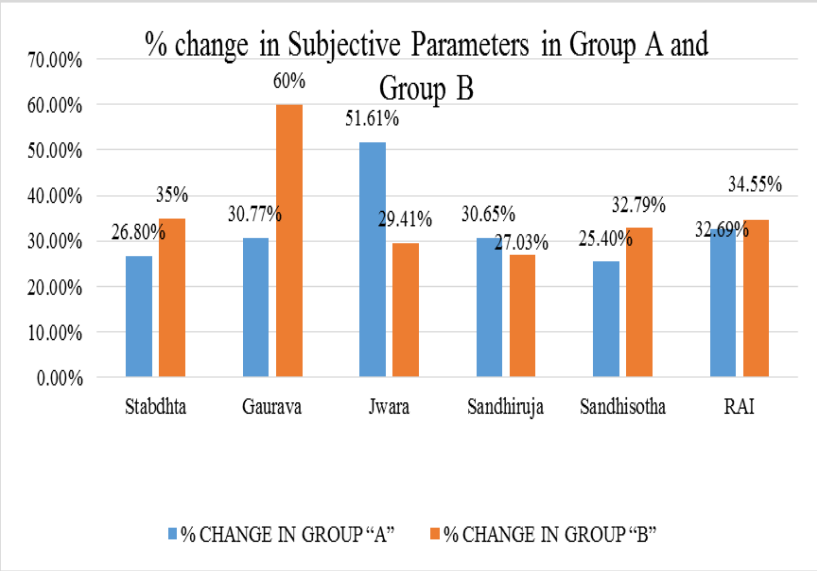
Variable	Groups	Mean	SD	SE	t value	P	S
DAS 28	A	5.216	0.68	0.1520	1.683	0.1006	IS
	B	5.549	0.5683	0.1271			
Grip Strength	A	0.45	0.5104	0.1141	0.7566	0.3121	IS
	B	0.40	0.5026	0.1124			
VAS	A	5.0	1.589	0.3554	1.751	0.0881	IS
	B	5.75	1.070	0.2392			
Walking Time	A	0.95	0.2236	0.05	2.135	0.03	S
	B	0.65	0.5871	0.1313			
ESR	A	32.20	16.634	3.72	0.2446	0.8081	IS
	B	33.55	18.234	4.077			

CRP	A	6.33	3.179	0.7109	2.789	0.008	S
	B	16.12	15.373	3.437			
RA Factor	A	132.06	237.92	53.2	1.062	0.2951	IS
	B	72.738	76.355	17.074			

(HS: Highly Significant S: Significant IS: In Significant)

Table No. 06: - Showing Interpretation of Result and % Change in Subjective Parameters of Group "A" and Group "B".

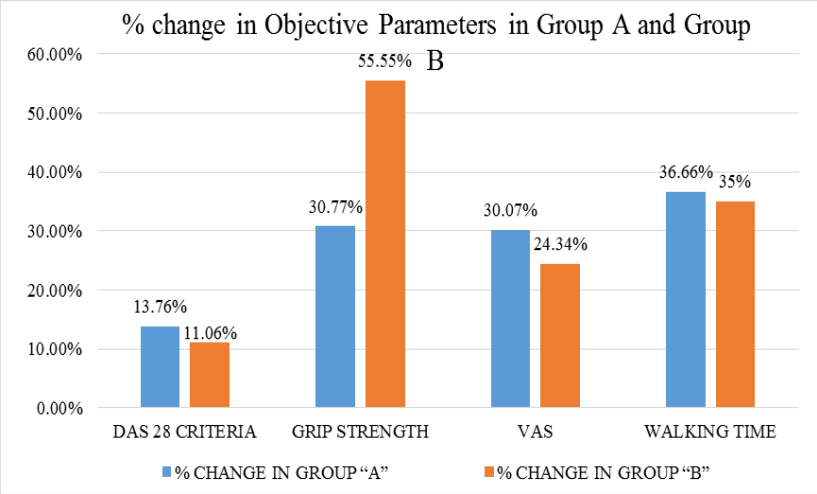
Subjective Parameters	GROUP A		GROUP B	
	Interpretation	% Change	Interpretation	% Change
Stabdhta	S	26.80%	HS	35%
Gaurava	S	30.77%	HS	60%
Jwara	HS	51.61%	S	29.41%
Sandhishoola	HS	30.65%	HS	27.03%
Sandhisotha	HS	25.40%	HS	32.79%
Rai (ritchie articular index)	HS	32.69%	HS	34.55%



Graph no.01: Distribution of % change in Subjective Parameters of both Groups.

Table No. 19: Showing Interpretation of Result and % Change in Objective Parameters of Group "A" and Group "B"

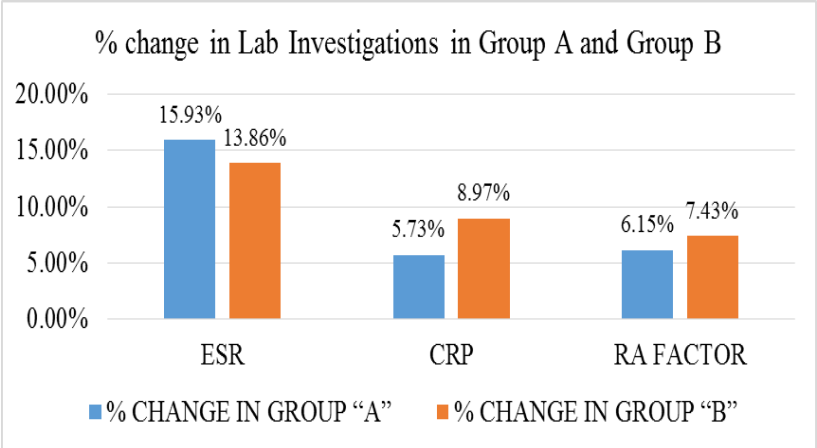
Objective Parameters	Group a		Group b	
	Interpretation	% Change	Interpretation	% Change
DAS 28 Criteria	HS	13.76%	HS	11.06%
Grip Strength	S	30.77%	HS	55.55%
Vas	HS	30.07%	HS	24.34%
Walking Time	HS	36.66%	S	35%



Graph no. 02: Distribution of % change in Objective parameters of both Groups.

Table No. 20: Showing Interpretation of Result and % Change in Laboratory Parameters of Group "A" and Group "B"

Laboratory parameters	GROUP A		GROUP B	
	Interpretation	% Change	Interpretation	% Change
Esr	HS	15.93%	HS	13.86%
Crp	HS	5.73%	S	8.97%
Ra factor	S	6.15%	HS	7.43%



Graph no.03: Distribution of % change in Lab Investigations of both Groups.

Table No. 21: Showing Intergroup Interpretation of Result in Subjective Parameters.

Subjective parameters	Interpretation
Stabdhta	NS
Gaurava	S
Jwara	S
Sandhishoola	S
Sandhisotha	NS
Rai (ritchie articular index)	NS

Table No. 22: Showing Intergroup Interpretation of Result in Objective Parameters.

Objective Parameters	Interpretation
DAS 28 CRITERIA	NS
GRIP STRENGTH	NS
VAS	NS
WALKING TIME	S

Table No. 23: Showing Intergroup Interpretation of Result in Laboratory Parameters.

Laboratory Parameters	Interpretation
ESR	NS
CRP	S
RA FACTOR	NS

DISCUSSION

On comparing the effect of two therapies on the basis of % change Group B (*Vaitarana Vasti)* provided better improvement than Group A (*Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam*) in *stabdhta*, gaurava, *sandhisotha*, RAI (Ritchie Articular index), grip strength, CRP and RA factor of the disease. Group A (*Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam*) provided better improvement than Group B in *jwara*, *sandhiruja*, DAS28 criteria, VAS (visual analogue scale), walking time and ESR but statistically there is no significant difference between both the groups in stabdhta, sandhisotha, RAI (Ritchie Articular Index), DAS 28 criteria, grip strength, VAS (Visual Analogue Scale), ESR and RA factor and statistically significant difference between both the groups in *gaurava*, *jwara*, *sandhiruja*, walking time and CRP.

DISCUSSION ON PROBABLE MODE OF ACTION OF *KALA VASTI* (*Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam*)

In this study, *Kala Vasti* (*Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam*) was selected as 1st trial drug. *Saindhvadya Taila Brhat* was mentioned by *Acharya Govind Das* in *Bhaishajya Ratnavali* in chapter no. 29 and contents of *Saindhvadya Taila Brhat* are *Saindhava Lavana, Sreyasi, Rasna, Satapuspa, Yamanika, Sarjika, Maricha, Kustha, Shunthi, Sauvarcala, Vida, Vaca, Ajamoda, Madhuka, Jiraka, Pooshkar moola, Pippali* and *Eranda taila. Rasnadashmoolakam* was mentioned by *Acharya Chakrapani Datta* in his famous compendium *Chakradatta* in chapter no. 25 and contents of *Rasnadasmoolakam* are *Dashmoola, Amrita, Eranda, Rasna, Shunthi* and *Devdaru*.

In *Saindhvadya Taila Brhat*, out of 13 drugs; 11 drugs having *katu rasa*, 7 drugs having *tikta rasa*. It helps in digestion of *ama* and it has *ashupaka* property through which it acts quickly at minute channels and in pacifying *vata dosha*. Out of 13 drugs; 11 drugs have *laghu guna*, 09 drugs have *tikshna guna* and 05 drugs have *ruksha guna* which helps in *amapachana* and *agni deepana* and 10 drugs out of 13 have *ushna veerya* and 09 drugs have *katu vipaka* which pacify both *vata* and *kapha dosha*. In *Rasnadashmoolakam*, out of 15 drugs; 12 have *tikta rasa*, 07 have *Kashaya rasa*, 05 have *katu rasa* and 09 drugs have *laghu guna*, 06 drugs have *ruksha guna* and 14 drugs have *ushna veerya* and 09 drugs have *katu vipaka*, 06 have *madhura vipaka*.

In the first stage of disease *amotapatti* is there and *Saindhvadya Taila Brhat* and *Rasnadashmoolakam* does *amapachana* as all the pharmacodynamics property i.e. *laghu, ruksha, tikshna guna, katu, tikta rasa, ushna veerya* are against the *guru, snigdha, pichila* and *shita* properties of *ama* also some effect of antioxidant property of drugs over *ama* (free radical) must be there. In the *srotoabhisyanda* it does *srotoshodhana* and relieves the symptoms of *shoola*, *sotha* by its *vednaprasamana* (analgesic) and *shothahara* (anti-inflammatory) action. As most of the drugs are *vata-kapha shamaka* and *agnimandya*, so it is very suitable for the *samprapti vighatana* of disease and to combat the main etiological factor (*ama, vata* and *kapha*) and *mandagni*, which are the root cause of *amavata*.

Discussion on Probable Mode of Action of *Vaitarana Vasti*

Vaitarana Vasti has been mentioned by *Chakradutta in Niruhadhikara* 73/32. Ingredients of *Vaitarana Vasti* are *Amalika (Emali), Guda, Saindhava, Gomutra* and *Tila taila.* In this *Vasti* maximum quantity is of *Gomutra* (Cow's Urine) which is having *Kshara Guna. Kshara* has the property of *Lekhana, Rukshana, Deepana* and *Pachana*; which are antagonist to *Ama* and are very much required in the conditions of *Amavata* to remove the *Ama*. But it must be kept in the mind that at the same time it may further vitiate the *Vata*. Thus, keeping this view in mind *Vaitarana* and *Saindhvadya Taila Anuvasana Vasti* (Therapeutic Oil Enema) was given in the format of *Kala Vasti*. *Saindhvadya Taila Brhat Anuvasana Vasti* (Therapeutic Oil Enema) removes the *Rukshta* of the body as well as control the *Vata* by *Snehana Guna*. All the ingredients of *Vaitarana Vasti* (Medicated enema) are *Vatashamaka* in nature. *Chincha* (Pulp of Tamarind) and *Guda* (Jaggery) are to be taken in *Vaitarana Vasti* should be in *Pakva* stage. Both are having *Madhura rasa*. *Purana Guda* to be used is *Laghu*, *Pathya*, *Agnivardhaka* and *Vatapittaghna*. *Saindhava* (Rock salt) due to its *Sukshma* and *Tikshana*

property help the *Vasti dravya* and *Taila* to reach up the molecular level. It is capable to liquefying the viscid matter and breaking it into minute particle. *Vaitarana Vasti* (Medicated enema) maintains the function of *Agni* and nourishes the body. It acts as *Srotoshodhaka* by its properties. Its *Srotoshodhaka* properties remove the *Avarana* of *Vata* by *Ama* and thereby counteracting pathology.

CONCLUSION

On comparing the effect of two therapies on the basis of % change Group B (*Vaitarana Vasti)* provided better improvement than Group A (*Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam*) in *stabdhta*, gaurava, *sandhisotha*, RAI (Ritchie Articular index), grip strength, CRP and RA factor of the disease. Group A (*Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam*) provided better improvement than Group B in *jwara*, *sandhiruja*, DAS28 criteria, VAS (visual analogue scale), walking time and ESR but statistically there is no significant difference between both the groups in *stabdhta*, *sandhisotha*, RAI (Ritchie Articular Index), DAS 28 criteria, grip strength, VAS (Visual Analogue Scale), ESR and RA factor and statistically significant difference between both the groups in *gaurava*, *jwara*, *sandhiruja*, walking time and CRP.

There were no adverse effects or complications found after completing the therapy. Therefore, it can be concluded that, administration of *Kala Vasti- Anuvasana Vasti* of *Saindhvadya Taila Brhat* and *Niruha Vasti* of *Rasnadashmoolakam and Vaitarana Vasti* is a safe and effective medicine for *Amavata*.

Limitations of study

- Present clinical study was done under limitation of time (18 months).
- The sample size of study was small. Small sample size makes it difficult to generalize the findings to the population at large.

Recommendations for Future research

- In the present study the size of sample was small and period of study was limited. In this context, it is suggested that the study should be continued with large sample and treatment for longer duration.
- In further studies ACPA (anti-citrullinated protein antibodies) should be measured before and after treatment. It is also predicting aggressive, erosive disease with extra articular

features and poor prognosis.

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