

Comparative Study of Clinical Effect of *Kshara-Basti* and *Virechana-Karma* in the Management of *Amavata* with Special Reference to Rheumatoid Arthritis

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Abstract Background: *Kshara Basti* and *Virechana Karma* as therapy for *Amavata* are indicated in Ayurveda. Ayurveda is having a crucial role in the management of *Amavata* with special reference to rheumatoid arthritis (RA) as a crippling disease. *Amavata* is having clinical appearance as comparable with RA. The line of treatment as mentioned by Chakradatta is to bring *Agni* to normal state for digestion of *Ama*, eventually to eliminate vitiated *Vata* and *Ama*. Thus, here *Kshara Basti* and *Virechana Karma* are selected for the present study as *Samshodhana* process which corrects all the above captions. **Objective:** To evaluate and compare clinical efficacy of *Kshara Basti* and *Virechana Karma* as therapy in *Amavata*. **Methods:** This was a randomized open-label, comparative clinical study. Total 35 randomly selected patients of *Amavata* were registered and screened and out of them 30 (15 patients in Group-A i.e. *Kshara Basti* and 15 patients in Group-B i.e. *Virechana-Karma*) were completed the treatment. *Kshara Basti* in the format of *Kala Basti* (as mentioned by Chakradatta) was given to the patients of *Basti* group and *Virechana Karma* as per Chakradatta was given to the patients of *Virechana karma* group. The effects of therapy in both groups were assessed by a specially prepared proforma. **Results:** The results of the study showed that both the groups showed significant relief in symptoms; however, compared to *Virechana karma* group, *Basti* group showed better result in the management of *Amavata*. Statistically significant improvement was found in ESR, RA factor (quantitative) and highly significant results were found in symptoms of *Amavata* (*Kshara Basti* results significant as compared to *Virechana karma*). Moderate improvement was seen in 80% of patients of *Basti* group (66.6% *Virechana karma* group), 6.6% patients got marked improvement in *Basti* group (no marked improvement in *Virechana* group), while mild improvement was found in 13.3% of patients of *Basti* group (33.3% for *Virechana karma* group). **Conclusion:** *Kshara Basti* and *Virechana Karma* have significant comparative activity in *Amavata*.

Keywords: complementary and alternative medicines, *amavata*, *Kshara Basti*, *Virechana Karma*, Ayurveda, rheumatoid arthritis

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1. Background

Amavata is the prime disease which makes the person crippled and unfit for an independent life. *Amavata* word is composed of two words *Ama* and *Vata*, the condition which is caused by accumulation of *Ama* and *Vata* is called *Amavata*. In terms of medicine *Ama* refers to the events that follow and the factors that arise because of impaired functioning of 'Agni' whereas in literal terms the word *Ama* means unripe, immature and undigested.

This 'Ama' is then carried by 'Vayu' and travels throughout the body and accumulates in the joints, at the weaker sites (*Khavaigunya*) and *Amavata* occurs [1]. It has similarities to clinical features associated with Rheumatoid Arthritis (RA). Rheumatoid Arthritis is a joint disorder which affects multiple joints at various sites. RA is a chronic systemic inflammatory disease [2].

In India, the prevalence of RA is estimated to be 0.8%. The prevalence rate of this disease is about 3% with a male to female ratio of 1:3 [3].

The principles of treatment of *Amavata* are *Langhana* and *Swedana*; and drugs having *Tikta*, *Katu Rasa*,

Deepana, Virechana, Snehapana and *Basti* properties [4]. In this present study an attempt is made to evaluate the effect of *Panchkarma* procedures i.e. *Kshara Basti* and *Virechana* in the management of *Amavata*.

Basti is very important therapy to manage *Vata-Dosha* and is called as *Ardha Chikitsa*. *Vata* is very important *Dosha* to be managed during treatment of any disease as other *Doshas* are handicapped without *Vata-Dosha*. *Virechanakarma* as a *Shodhana*-therapy is described as the effective management of *Amavata*. As it is the therapy for the *Sthanika Pitta Dosha*, it is responsible for *Agnivardhana* and evacuation of *Ama*, which is the main etiological factor of this disease [5]. So, in the present study, *Kshara Basti & Virechana karma* has been selected as *Shodhana Chikitsa* which is mentioned in *Chikitsa Sutra* described by Chakradatta.

Thus, a clinical study was planned to assess the clinical effectiveness of *Kshara basti* and *Virechana karma* and to compare the effect of these two therapies in the treatment of *Amavata*.

2. Methods

This clinical study was conducted at Department of Panchakarma, Rajiv Gandhi Government Post-graduate Ayurveda College, Paprola, Himachal Pradesh (India) to determine the the clinical effectiveness of *Kshara basti* and *Virechana karma* in *Amavata*.

2.1. Ethical Consideration

The study was approved by the Institutional Ethics Committee of Rajiv Gandhi Government Post-graduate Ayurveda College, Paprola (IEC/2013/372). Patients were enrolled in the study only after voluntary written informed consent.

2.2. Quality Testing of Ayurvedic Medicines from Drug Testing laboratory, Joginder-Nagar, Mandi

The Ayurvedic Medicines were tested in the laboratory for Quality and whether comply with the API (Active Pharmaceutical Ingredient) standards (Ref. DTL.P/15/13-848/3).

2.3. Selection of 'Amavata' Patient

After ethical approval from Institutional Ethics Committee; 35 IPD patients were selected for screening and 30 IPD were randomized and enrolled in 2 groups (after taking voluntary informed consent from patients) from the Department of *Kayachikitsa*. For this, patients fulfilling the criteria for the diagnosis of the disease were registered for the present study according to their age (between 18 to 70 years) but irrespective of their sex, religion, occupation and other parameters. Both acute and chronic phases of *Amavata* patients were taken for the study, following the ACR criteria of the diagnosis of RA in modern medicine and the clinical features of *Amavata* described in *Madhava Nidana* [6].

2.4. Study Design

Single centered, open-label randomized study.

2.5. Inclusion Criteria

The patients between the age group of 18-70 years of either sex presenting with the clinical features of *Amavata* like pain, stiffness and swelling in multiple joints along with features of *Ama* like loss of appetite, indigestion and fever. Patient diagnosed for RA on the basis ACR criteria.

2.6. Exclusion Criteria

Pregnant women and lactating mother;

Patients suffering from paralysis, neurological disorder, gout, cardiac disease, diabetes mellitus, hypertension, chronic kidney diseases, osteomyelitis;

Patients contraindicated for *Basti* and *Virechana* as mentioned in *Samhitas*. Patients having the classical features of *Amavata* like *Angamarda*, *Aruchi*, *Trishna*, *Alasya*, *Jwara*, *Sandhishula*, *Sandhishotha* [7], and modern parameters of Rheumatoid arthritis (RA) like morning stiffness, pain, tenderness, swelling, fever, raised E.S.R. etc. were included for the present study [8].

The criteria for diagnosing RA [as lay down by American Rheumatism Association (A.R.A.)] in 1987 was also taken into consideration [9]. Both seropositive and seronegative RA factor cases RA. Chronicity for more than 10 years, having severe crippling deformity, cardiac disease, pulmonary- tuberculosis and diabetes mellitus patients were excluded.

A detailed research Proforma was prepared incorporating all the signs and symptoms seen in the disease.

2.7. Randomization

Patients were screened and randomized on first cum first served basis. The simple randomization table was generated through computer based standard software program.

2.8. Investigations

The routine haematological and biochemical investigation, RA factor and C-reactive protein (C.R.P.) test were done before and after treatment. Routine stool and urine examination were conducted during the study to see for any changes in the biological system.

2.9. Grouping

A total of 30 clinically diagnosed and registered patients of *Amavata* were divided randomly by lottery method into two groups. Each group had 15 patients.

Group I: Kshara-Basti Group

Amount of all dravyas as mentioned in the text was taken in its half quantity keeping in the mind the body strength (Rogibala) of the patients.

Table 1. *Kshara-Basti* Ingredients

Pachana	Nagar churna (Ref-Chakradatta)
	1-3 gm BD with Kanji 10-20 ml for 3 days.
Anuvasana Basti (Ref. Chakradatta)	Brihata Saindhavadi Taila- 30 - 50 ml.
Kshara Basti (Ref- Chakradatta)	Saindhava - 5 gm
	Shatahva - 5 gm
	Gomutra - 200 ml
	Amlika - 50 gm
	Guda - 50 gm

Group II: Virechana-Karma Group

Amount of all *dravyas* as mentioned in the text was taken in its half quantity keeping in the mind the body strength (*Rogibala*) of the patients.

Table 2. *Virechana-Karma* Ingredients

Pachana	Nagarchurna (Chakradatta)	1-3 gm BD with Kanji 10-20 ml for 3 days.
Snehapana	Shunthighrita (Chakradatta)	Patients selected were given <i>Sunthi Ghrta</i> for <i>Snehapana</i> as <i>purva karma</i> in the dose starting from 30-50 ml as per <i>Kostha</i> and <i>Agni</i> of the patient in increasing dose till the appearance of <i>samyak snehan lakshana</i> .
Abhyanga	Brihat Saindhavadi Taila	75 – 100 ml sitting as per requirement of patient.
Virechanakalpa	Haritaki Kwatha (Chakradatta) 30 ml + Eranda Taila 30ml	
Samsarjankram	According to <i>shodhana</i>	

2.10. Criteria for Assessment

The results of the therapy were assessed based on clinical signs and symptoms mentioned in the Ayurvedic classics. The improvements in the condition of patients were assessed based on *Roga Bala*, *Agni Bala*, *Deha Bala*, *Chetasa Bala* and as well as by American Rheumatism Association (ARA 1987) criteria for degree of disease severity [10].

A. Clinical assessment

The changes observed in the signs and symptoms were assessed by adopting suitable scoring method and by using appropriate clinical tools. The details of scoring pattern adopted for assessment of clinical sign and symptoms are given below:

Table 3. *Amavata*: Clinical Signs and symptoms

Symptoms	Grades	Score
<i>Sparsha- Asahyata</i>	No <i>Sparsha-Asahyata</i>	0
	Subjective feeling of tenderness	1
	Wincing of face on pressure & withdraw of concerned part	2
	Resists touching	3
<i>Sandhi- Shula</i>	No <i>Sandhi-Shula</i> /pain	0
	Mild pain of low intensity, not hamper in daily routine work	1
	Moderate pain hampers the daily routine work	2
	Severe pain causing definite interruption in routine work	3
<i>Sandhi- Shotha</i>	No Swelling	0
	Mild Swelling	1
	Moderate Swelling	2
	Severe Swelling	3
<i>Sandhi- Graha</i>	No stiffness or stiffness lasting for 5min	0
	Stiffness lasting for 5 min to 2 hours	1
	Stiffness lasting for 2 to 8 hours	2
	Stiffness lasting for more than 8 hours	3

B. Degree of disease activity

In the above criteria the maximum score can be calculated, which represents an average of grade 3 (severely active). The grade of disease is denoted by figures 0 – 3.

Table 4. Degree of Disease Severity as per ARA

For diagnostic as well as for assessment purpose, the degree of disease activity was estimated based on criteria laid down by American Rheumatism Association (1987)				
Grade	0	1	2	3
Haemoglobin (gm%)	>12.5	12.4 to 11.0	10.9 to 9.5	<9.5
ESR (Westergreen-1st Hr)	0-20	21-35	36-50	>50
General function	All activity-no difficulty	Most activity with difficulty	Few activity care for self	Little self-care
Relief as per Patient	Fine	Almost well	Good	Bad
Physician's Opinion- RA	Inactive	Minimally active	Moderately active	Severely active
Fatigue	Not there	Full time work despite fatigue	must interrupt work to rest	Fatigued & requiring long term rest
Grip power	>120	102-120	82-100	62-80
Foot Power	25 to 21	20 to 16	15 to 10	<10
Walk time (for 50 m/s)	<30	31-40	41-50	51-60

Table 5. Comparative effects of Test-Therapies Kshar-Basti in Group-A and Virechana-Karma in Group-B on overall improvement in cardinal symptoms of Amavata in the trial (By paired t-test)

Parameters	Group	N	Mean Score		Mean Diff	%Relief	SD ±	SE±	't'	p
			BT	AT						
Sandhi-Shula	A	15	1.8	0.7	1.06	59.25	0.458	0.118	9.025	<0.001
	B	15	1.6	0.6	1	62.5	0.655	0.169	5.916	<0.001
Sandhi-Shotha	A	15	1.66	0.6	1.06	64	0.458	0.118	9.025	<0.001
	B	15	1.6	0.6	1	62.5	0.535	0.138	7.246	<0.001
Sparsha-Asahyata	A	15	2.26	0.93	1.33	58.88	0.488	0.126	10.583	<0.001
	B	15	1.8	0.66	1.13	62.36	0.516	0.133	8.5	<0.001
Sandhi-Graha	A	15	1.93	0.73	1.2	62.06	0.594	0.153	6.089	<0.001
	B	15	2.13	0.86	1.26	53.37	0.594	0.153	8.264	<0.001

BT: Before Treatment and AT: After Treatment.

From above table, the comparative effects of therapies i.e. *Kshar-basti* and *Virechana karma* have significant improvement in *Sandhi-shula*, *sandhi-shotha*, *sparsha-asahyata*, *sandhi-graha* in both group-A and group-B.

Table 6. Comparative effects on General symptoms of Amavata by Test-Therapies Kshar-Basti in Group-A and Virechana-Karma in Group-B

Sr No	Parameters	Group	N	Mean BT	Mean AT	Diff	%Relief	SD ±	SE±	t	p-value
1	Angamarda	A	15	1.73	0.6	1.13	65.38	0.64	0.165	6.859	<0.001
		B	15	1.73	0.6	1.13	65.38	0.64	0.165	6.859	<0.001
2	Apaka	A	14	1.2	0.26	0.93	77.77	0.258	0.066	14	<0.001
		B	14	1.2	0.26	0.93	77.77	0.258	0.066	14	<0.001
3	Aruchi	A	15	1.8	0.8	1	55.55	0.378	0.097	10.247	<0.003
		B	15	1.81	0.8	1	55.5	0.370	0.096	10.24	<0.005
4	Gauravata	A	12	1.53	0.86	0.66	43.47	0.617	0.159	4.183	<0.004
		B	12	1.5	0.8	0.6	43.44	0.62	0.15	4.18	<0.004
5	Hritgraha	A	15	1.1	0.26	0.86	76.47	0.64	0.16	5.245	<0.005
		B	15	1.13	0.21	0.84	76.46	0.6	0.165	5.24	<0.005
6	Jwara	A	15	1.32	0.46	1.06	63.6	0.54	0.13	6.5	<0.001
		B	15	1.53	0.44	1.03	63.56	0.594	0.153	6.959	<0.001
7	Trishna	A	14	1.73	0.66	1.06	61.53	0.594	0.153	6.959	<0.05
		B	14	1.7	0.76	1.04	61.3	0.54	0.13	6.9	<0.05

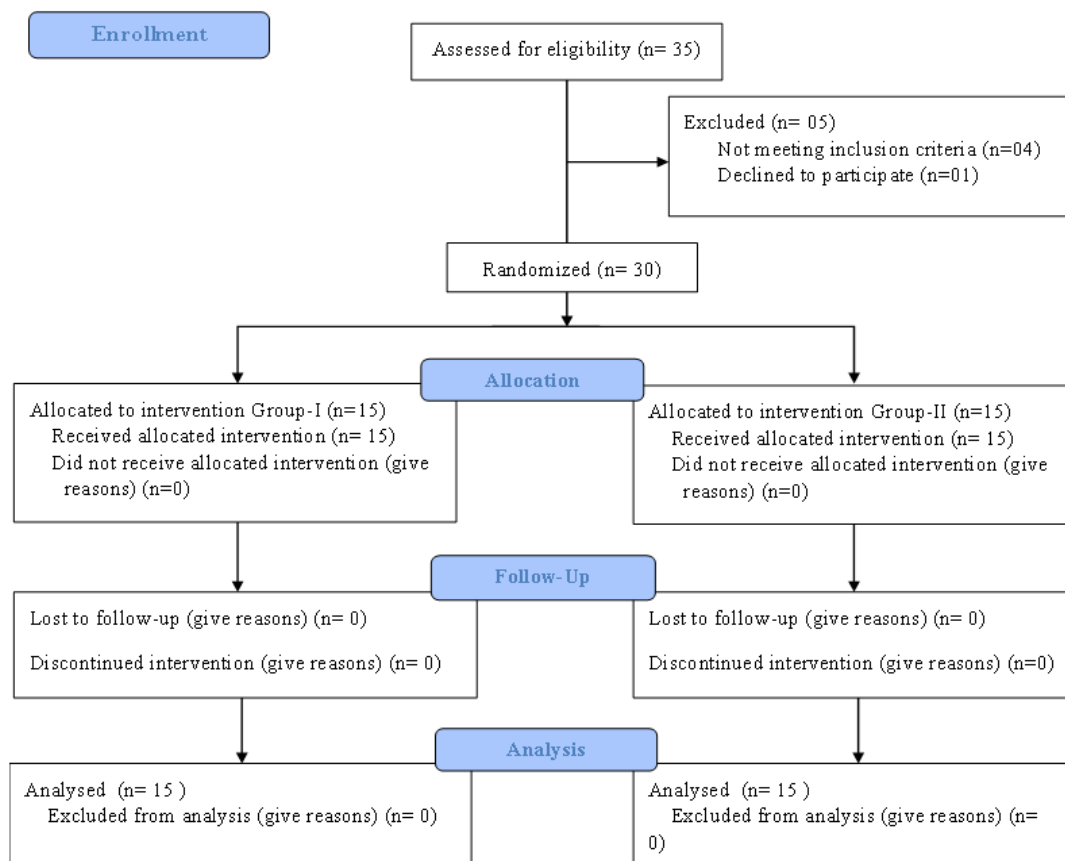
Table 7. Comparative effects on Associated symptoms of Amavata by Test-Therapies Kshar-Basti in Group-A and Virechana-Karma in Group-B

Sr N	Parameters	Group	N	Mean BT	Mean AT	Diff	%Relief	SD ±	SE±	t	p-value
1	Agni Daurbalya	A	15	1.8	0.46	1.33	74.07	0.488	0.126	10.583	<0.001
		B	14	1.06	0.26	0.8	75	0.561	0.145	5.527	<0.001
2	Alasya	A	15	1.66	0.33	1.33	80	0.617	0.159	8.367	<0.05
		B	15	2.06	1	1.06	51.61	0.594	0.153	6.959	<0.05
3	Bahumutrata	A	15	1.33	0.53	0.8	60	0.414	0.107	7.485	<0.001
		B	15	1.46	0.66	0.8	54.54	0.676	0.175	4.583	<0.03
4	Daha	A	10	0.66	0.13	0.53	80	0.516	0.133	4	<0.001
		B	10	0.73	0.26	0.46	63.63	0.516	0.133	3.5	<0.01
5	Jadya	A	15	1.46	0.6	0.86	59.09	0.516	0.133	6.5	<0.001
		B	13	1.13	0.33	0.8	70.58	0.414	0.107	7.483	<0.001
6	Kukshikathinya	A	7	0.46	0.13	0.33	71.42	0.488	0.126	2.646	<0.05
		B	7	0.73	0.26	0.46	63.63	0.516	0.133	3	<0.01
7	Nidraviparyaya	A	14	1.26	0.33	0.93	73.68	0.458	0.118	7.887	<0.001
		B	15	1.46	0.66	0.8	54.54	0.676	0.175	4.583	<0.001
8	Vairasyata	A	15	1.46	0.53	0.93	63.63	0.594	0.153	6.089	<0.05
		B	11	0.86	0.33	0.53	61.53	0.64	0.165	3.228	<0.01
9	Vidvibandha	A	15	1.26	0.13	1.13	89.47	0.332	0.09	12.475	<0.001
		B	15	1.46	0.26	1.2	81.81	0.414	0.107	11.225	<0.001

3. Statistical Analysis

The available data was analyzed for demographic parameters, cardinal signs and symptoms of *Amavata* and results in both groups. Total allocation of 30 patients was planned and was randomized in two groups using SPSS software (version16). Demographic data and baseline information was analyzed by descriptive method and is presented with summary statistics (*n*, mean, standard deviation, range) for continuous variables, whereas counts and percentages for categorical variables. These summaries are presented as per these two treatment groups.

3.1. Consort Flow Diagram

**Figure 1.** Flow Diagram

4. Results

In this study majority of patients, i.e. 71.87% belonged to the age group of 31-50 years and 71.87% were female.

The 90.62% patients were Hindu, 81.25% were married, 53.12% patients were housewives, 61.24% were from low income group and 24.99% had history of smoking or alcohol while 56.30% of the patients were history of consuming analgesic and steroids.

Majority of the patients had *Vata-Kapha Prakriti* (53.12%) and 40.62% had *Vata-Pitta Prakriti*. The percentage of patients in other groups considered was as follows: *Mandagni* (93.75%). 21.87% of the patients had positive family history of RA, 53.12% of patients had insidious onset and 78.13% had chronicity of more than 2 years.

In this study, RA factor was found positive in 62.50% of patients and raised E.S.R found in 73.35% of the patients. Most of the patients of this series i.e. 59.37% were having *Madhyam Abhyavarana Shakti* while 53.12% were having *Avara Jarana Shakti*. The etiological factors of *Amavata* found were *Viruddhahara* (84.94%), *Atiguru* (27.35%), *Bhojanattora Vyayama* (81.10%), *Divaswap* (62.44%), *Vishamashana* (83.22%), and *Snigdha Ahara* (27.33%).

The chief complaints like *Angmarda*, *Aruchi*, *Alasya*, *Shoonatam cha anganam* were found in 94.56% patients while *Trishna* was found in 93.75%, *Jwara* and *Apaka* were found in 93.87% patients and *Gauravata* was found in 90.62%.

With respect to cardinal symptoms, *Sandhi-shula* and *Sparsha-Asahyata* were observed in all the patients, i.e., 100%, followed by *Sandhishotha* in 92.33% of patients. Maximum patients experienced *Vid-Vibaddhata* (98.02%), 96.87% experienced *Agni-daurbalya* and *Nidraviparyaya* followed by 90.62% for *Hritgraha* and *Jadya*.

It was observed that wrist joint was involved in 93.75% of the patients. 84.37% had proximal Interphalangeal Joint (P.I.P) and knee joints, 81.25% elbow and ankle joint involvement. 78.12% were reported with Distal Inter Pharyngeal joint involvement, 65.62% of patients were reported with Metacarpal joints involvement, 62.5% of patients had Neck joint involvement, 59.37% of patients had Shoulder joint and Metatarsal joint involvement, 50% patients had Hip joint involvements.

5. Discussion

Agnimandya (*mandya*=Low functioning of *Agni*) is an important main factor responsible for the formation of *Ama*.

The etiological factors like *Guru Ahara*, *Viruddhahara*, *Viruddha Cheshta*, *Mandagni*, *Snigdhabhuktavata Vyayama* are responsible for *Amavata* [11]. Sedentary lifestyle and changes in daily-routine and dietary patterns are responsible factors for the manifestation of disease.

Table 8. The comparative effects of both therapies on *Amavata* on 30 IPD-patients belonging to Group-A and Group-B

Effects of Therapy	Group A (n=15)		Group B (n=15)	
	No. of Pts.	%	No. of Pts.	%
Unchanged	0	0	0	0
Mild Improvement	2	13.33	5	33.33
Moderate Improvement	12	80	10	66.66
Marked Improvement	1	6.66	0	0
Complete remission	0	0	0	0

The effects of both *Basti* and *Virechana-karma* therapy was mentioned in above Table 8. In most of the patients, moderate improvement found in both therapies (73.33%). 80% of the Group-A patients and 66.66% of the Group-B patients had moderate improvement.

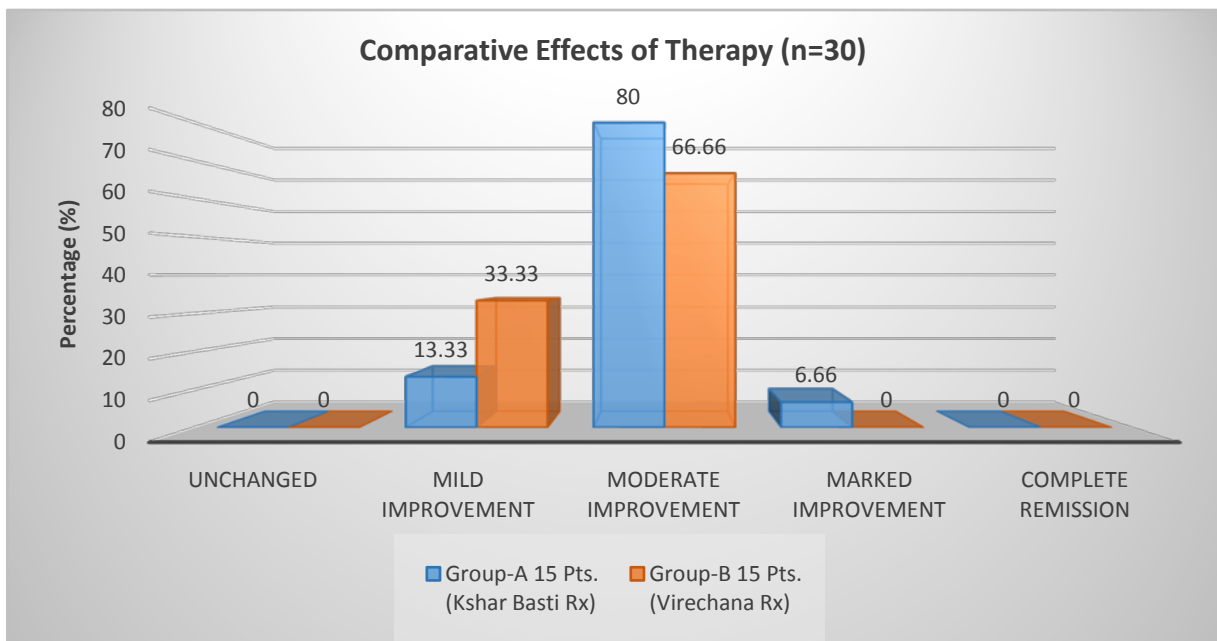


Figure 2. Comparative effects of both therapies in Group-A (n=15) and Group-B (n=15)

The overall effects of therapy are mentioned as below

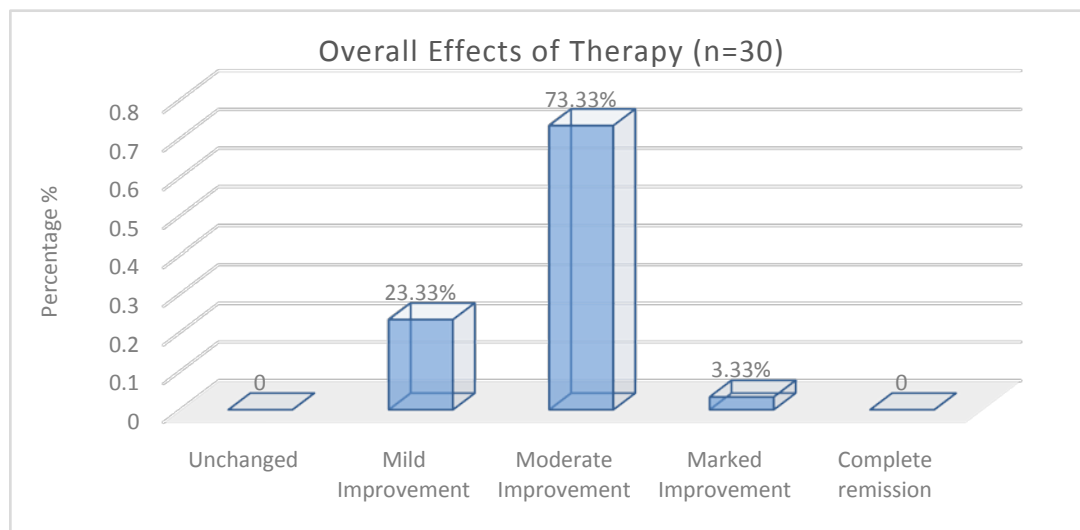


Figure 3. Overall effects of both therapies in study population (n=30)

The overall effects of therapy indicate that 73.33% of the patients (n=22/30) has moderate improvement while 23.33% of the total study population (n=07/30) has mild improvement. Only 1 patient has marked improvement.

2016: Sasane P & *et al* had done the comparative clinical evaluation efficacy study *Alambushadi Ghana Vati* (Group-A) and *Vaitarana Basti* (Group-B) in the management of *Amavata* in Jaipur and found that intergroup comparison showed that there was no major difference in efficacy of trial drug of both groups. However, *Angmarda* ($p < 0.05$) which there was statistically significant difference that Group-A provided better result than Group-B. In Group-A, excellent relief was found in 6.66% of patients, while significant relief in 46.66%, moderate relief in 33.33%, whereas mild relief in 13.33% of the patients, while in Group-B – excellent relief was found in 20% of patients, while significant relief in 60%, moderate relief in 13.33%, whereas mild relief in 6.66% of the patients [11].

In this our study, moderate improvement was seen in 80% of patients of *Kshara Basti* group (66.6% *Virechana karma* group), 6.6% patients got marked improvement in *Basti* group (no marked improvement in *Virechana karma* group), while mild improvement was found in 13.3% of patients of *Basti* group (33.3% for *Virechana karma* group).

2012: Thanki K & *et al*, done the study effect of *Kshara Basti* along with *Nirgundi Ghana Vati* on *Amavata* and found that moderate improvement was seen in 40% of patients, 35.56% patients got marked improvement, while mild improvement was found in 24.44% of patients. Effect of therapy on chief complaints such as *Sandhishula*, *Sandhishotha*, *Sandhistabdhata* and *Sandhisparsa-Asahyata* was found to be statistically highly significant ($P < 0.001$) [12]. And, the study done by Pandey S & *et al* in 2012 was on clinical efficacy of *Shiva Guggulu* and *Simhanada Guggulu* in *Amavata*. On analysis of the results, it was found that *Simhanada Guggulu* provided better results as compared to *Shiva Guggulu* in the management of *Amavata* [13].

In this our study, intergroup comparison of effects of test-therapies *Kshara Basti* in Group-A and *Virechana Karma* in Group-B on overall improvement in cardinal symptoms of *Amavata* like *Sandhishula*, *Sandhishotha*, *Sandhistabdhata* and *Sandhisparsa-Asahyata* was studied and found no significant difference between these two therapies.

2010: The study done by Khagram R & *et al*, observed the clinical effect of *Matra Basti* (Group-A) and *Vatari Guggulu* (Group-B) in the management of *Amavata* in Jamnagar. After assessing the overall effect of therapy, it was seen that marked improvement and moderate improvement was more in group-A by 52% and 42% respectively while in group-B marked improvement was only 11.32% and moderate improvement was 28.30% respectively [14].

In our study, the moderate improvement seen more in group-A by 80% and in group-B by 66.66% while 13.33% mild improvement in group-A and 33.33% mild improvement in group-B. Marked improvement was found only in group-A as 6.66%.

6. Conclusion

Madhava-Nidana guides that *Ama* and *Vata* being contradictory in nature make it difficult to plan the line of treatment in *Amavata*. In this study, although the improvement was statistically highly significant in both the groups, the *Kshara Basti* group (group A) showed comparatively better relief than the *Virechana-Karma* group (group B). Thus, *Basti* can be thought of as an ultimate solution for the eradication of *Vata Dosha*, *Virechanakarma* as a therapy for the *Sthanika Pitta Dosha*, it is responsible for *Agnivardhana* and evacuation of *Ama*, which is the main etiological factor of this disease. On comparing the effect of two therapies it can be concluded that *Kshara-Basti* provides significantly better relief than *Virechana-Karma* in most of the signs and symptoms of the disease.

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