



Research Article

A COMPARATIVE CLINICAL STUDY OF *KHANDA SHUNTHI* AND *PRASARNI AVLEHA* IN THE MANAGEMENT OF *AMAVATA* WITH SPECIAL REFERENCE TO RHEUMATOID ARTHRITIS

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ABSTRACT

Background: *Amavata* is the most common form of inflammatory arthropathy seen in India. Among adult population below the age of 50 years this is the most common form of arthritis. For the present study, on *Amavata* as shaman therapy, *Khanda Shunthi* and *Prasarni Avleha* the *Ushnaveeryadravya* medicaments were chosen.

Aims & Objective: The present research work aimed at to evaluate efficacy and establish safe use of *Khanda Shunthi* and *Prasarni Avleha* in *Amavata*.

Materials & Methods: 40 subjects of *Amavata* fulfilling the inclusion criteria were selected from OPD and IPD of Desh Bhagat Ayurvedic Hospital, Mandi Gobindgarh, Punjab and randomly divided into two groups, group A and B, comprising each of 20 patients. Group-A subjects received *Khanda Shunthi* for 60 days, Group-B subjects received *Prasarni Avleha* for 60 days. Assessments were done on 0th and 60th day of treatment.

Results and Conclusions: In both the groups, highly significant results were observed in all the cardinal parameters with P value for fever and Hb are greater than 0.05 hence there is no significant difference in effect of Group A and Group B on fever and Hb. P values for all other symptoms are less than 0.05 hence we conclude that there is significant difference in effect of group A and group B on pain, swelling, stiffness, fever, ESR, walking time and grip strength. On comparison group A treatment is more effective than group B for all assessment criteria.

INTRODUCTION

Ayurveda, the ancient medical science of India has got the treasure of effective remedies for various chronic and intractable diseases. Because of changing lifestyle, social structure, environment and dietary habits of modern era incidences of many ailments are increasing day by day. Growing occurrence of *Amavata* is also one of the outcomes of this new way of life. It is a common chronic inflammatory joint disease in which joints become swollen, painful, and stiff. It is a debilitating illness considering its chronicity and complications. On the basis of etiology and clinical features *Amavata* can be correlated with Rheumatoid arthritis (RA).

Rheumatoid arthritis (RA) is the most common form of inflammatory arthropathy seen in India. Among adult population below the age of 50 years this is the most common form of arthritis. There are several reports on the frequency of RA in different populations group. A study from West Bengal (1997) gave the prevalence rate as 4.48 to 4.63 per 1000 populations. Seropositive disease occurred in two-third among them. The prevalence of RA is 0.5% of the Indian population. In the rural part it is 0.7%. Among the connective tissue disease, RA is by far the commonest.^[1]

The word *Amavata* is made up of a combination of two words, *Ama* and *Vata*.^[2] The disease is mainly due to derangement of *Agni*, including, *Jatharagni*, *Dhatvagni* and *Bhutagni*, which results in the formation of *Ama*. *Ama* gets circulated throughout the body by the vitiated *Vata dosha* and track down in the *Sandhis* (joints), causing swelling, pain, tenderness and stiffness over the big and small joints.^[3]

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Therefore, it has taken the foremost place among the joint disorders. It continues to pose challenge to physician due to severe morbidity and crippling nature and claiming the maximum loss of human power making it a biggest world wise burning problem irrespective of races.

For the present study, on Amavata as Shamana therapy with “Khanda Shunthi” and “Prasarniavleha”

the *Ushna Veerya Dravya* medicaments were used. The drugs are mentioned in *Bhavaprakash Madhyam Khanda* in the context of *Amavata*.

Trial Drugs

Khanda Shunthi and *Prasarni Avleha* are mentioned in *Bhava Prakash (Madhyam Khanda)* under *Aamavata rogadhikara* were used for trial.

Table 1: Khanda Sunthi- Main ingredients of Khanda Shunthi

S.No.	Ingredients of Khand Shunti	Part used	Proportion
1	<i>Shunthi (Zingiber officinale)</i>	Rhizome	32 parts
2	<i>Go Ghrita</i>	Cow’s Ghee	80 parts
3	<i>Go Dugdha</i>	Cow’s milk	128 parts
4	<i>Khanda Sharkara</i>	Sugar candy	200 parts
Prakshep dravya			
1	<i>Shunthi (Zingiber officinale)</i>	Rhizome	1 Part
2	<i>Maricha (Piper nigrum)</i>	Fruit	1 Part
3	<i>Pippali (Piper longum)</i>	Fruit	1 Part
4	<i>Twak (Cinnamomum zeylanicum)</i>	Bark	1 Part
5	<i>Tejapatra (Cinnamomum tamal)</i>	Leaf	1 Part
6	<i>Ela (Elettaria cardamomum)</i>	Fruit	1 Part

Main Ingredients of Khanda Shunthi



Table 2: Prasarni Avleha - Main ingredients of Prasarni Avleha

S.No.	Ingredients	Part used	Proportion
1	<i>Prasarni kwatha (Paederia foetida)</i>	Whole Plant	1 Adhaka (2.56kg)
2	<i>Guda (Jaggery)</i>	-	1 Prastha (80 grams)
Prakshep dravya			
1	<i>Pippali (Piper longum)</i>	Fruit	1 Part
2	<i>Pippalimoola (Piper longum)</i>	Root	1 Part
3	<i>Chavya (Piper chaba)</i>	Fruit	1 Part
4	<i>Chitraka (Plumbago zeylenica)</i>	Root	1 part
5	<i>Shunthi (Zingiber officinale)</i>	Rhizome	1 Part

Main Ingredients of Prasarni Avaleha



Khanda Shunthi and *Prasarni Avaleha* were prepared in Desh Bhagat Ayurvedic Pharmacy, Mandi, Gobindgarh, Punjab. The quality of ingredients and final product was ensured by the experts from the Department of Dravyaguna and Rasashasrta of the Institution.

AIM AND OBJECTIVES

1. To review concept, etiopathogenesis and principles of management of disease *Amavata* (R.A) from both Ayurvedic and modern point of view.
2. To evaluate the efficacy of *Khanda-Shunthi* in *Amavata*.
3. To evaluate the efficacy of *Prasarni Avaleha* in *Amavata*.
4. To establish safe and effective medicine for treatment of *Amavata*.

MATERIAL AND METHODS

The present study comprises of two components as follows:

- Demographic and clinical study in *Amavata* patients.
- Clinical assessment of therapeutic study of trial drugs in patients of *Amavata*.

Hypothesis

- Will there be any significant difference between the efficacy of *Khanda Sunthi* and *Prasarni Avleha* during the management of *Amavata*.
- H₀: There will be no significant difference between the efficacy of *Khanda Sunthi* and *Prasarni Avleha* in both the trial groups at 0.05 level of significance.
- H₁: There will be significant difference between the efficacy of *Khanda Shunthi* and *Prasarni avleha* in both the trial groups at 0.05 level of significance.

Clinical Study

Patients suffering from *Amavata* were selected from OPD Desh Bhagat Ayurvedic Pharmacy, Mandi Gobindgarh and IPD of Desh Bhagat Hospital, Mandi Gobindgarh, Punjab, after fulfilling the inclusion and exclusion criteria.

Clinical Data

Sample size

Total number of patients taken for study were 40 excluding dropouts of *Amavata* were selected from

OPD/ IPD of Desh Bhagat Hospital, Mandi, Gobindgarh (PB).

Study Design: Randomized, Parallel group, comparative trial.

- **Screening:** 57 patients were attending the OPD/ IPD of *Kayachikitsa* department with symptoms and signs of *Amavata* i.e., Rheumatoid Arthritis considered for inclusion in the study.
- **Consent:** Written and informed consent of patients had taken before inclusion in the trial.
- **Enrolment:** 49 Screened *Amavata* patients, who will give their consent and fulfil the inclusion criteria be selected for the study.

Grouping of Patients

There will be only two group's i.e.

Trial Group A: 20 patients were selected for the trial in this group. *Khanda Shunthi* was given in the dose of 10gm. Two times a day with lukewarm water.

Trial Group B: 20 patients were selected for the trial. *Prasarni avleha* was given to patients of this group in the dose of 10gm. Twice a day with lukewarm water.

Dropout Patients- 9 patients

40 Patients were participated for complete clinical trial.

Follow-up: All the patients were called for follow-up after every 15days.

Final Study Visit: All patients were assessed clinically after completion of the trial (i.e. after 60 days)

- **Duration of trial:** The total duration of the trial drug is 60days with evaluation at intervals of every 15days.
- **Follow-up:** The patients after putting into trial advised to come for follow up after every 15th, 30th, 45th, and 60th days.

Inclusion Criteria

1. Patients of *Amavata* with the history less than 5 years.
2. Both male female patients age between 15 to 65 years.
3. Patients having signs and symptoms of *Amavata* of any *Dosha Anubandha* mentioned in Ayurvedic text and modern text.

Exclusion Criteria

1. A patient of *Amavata* having history of more than 5 years.
2. Patient below 15 and above 65 years of the age
3. Patients with complications like deformity, loss of functions and *Granthi*
4. Pregnant women and lactating mother
5. Patients with Rheumatic fever
6. RA of Spine
7. Patients of *Amavata* having the systemic diseases.

Parameters for assessment

Subjective Parameters

The Symptoms of *Amavata* in Ayurvedic text and modern texts like *Shoola, Shotha, Jadya, Vaivarnyata*.

Joint Pain (*Sandhi Shoola*)

Table 3: Showing Joint Pain Grading

Score	Joint Pain Status
0	No Pain
1	Mild Pain
2	Pain on movement & relieved on rest
3	Constant Pain
4	Severe Pain disturbing sleep

Swelling of Joints (*Sandhi Shotha*)

Table 4: Showing *Sandhi shotha* grading

Score	Status
0	No Swelling
1	Mild Swelling
2	Moderate Swelling
3	Severe Swelling without loss of movements
4	Severe Swelling with loss of movements

Stiffness (*Stabdhatā*)

Table 5: Showing Stiffness Grading

Score	Status
0	No stiffness
1	Stiffness lasting for few minutes to 1 hour
2	Stiffness lasting for 1 to 8 hours
3	Stiffness lasting for more than 8 hours but not through-out the day
4	Throughout the day

STATISTICAL ANALYSIS

Study statistically analyzed with Wilcoxon matched pairs test, Mann-Whitney U test.

Outcome of Therapies on *Shula* (Pain)

Table 10: Table-Outcome of Therapies on *Shula* (Pain)

Pain	Median		Wilcoxon Signed Rank	P-Value	% Effect	Result
	BT	AT				
Group A	3	0.5	-4.028 ^a	0.000	82.8	Significant
Group B	3	1	-3.992 ^a	0.000	66.7	Significant

Jwara (Fever)

Table 6: Showing fever grading:

Score	Status
0	No Fever
1	Mild fever
2	Moderate fever
3	High fever

Objectives Parameters

1. Hb%
2. ESR
3. Walking time
4. Grip strength

Grip strength: Patient's grip strength is assessed before and after treatment according to the readings in the grip strength meter in terms of pound.

Haemoglobin

Table 7: Showing Haemoglobin

Haemoglobin gm%	Grade
12.5 or more	0
12.4 to 11gm%	1
10.9 to 9.5gm%	2
Less than 9.5%	3

ESR

Table 8: Showing ESR Grading

ESR	Lab Value (mm/h)	Grade
Normal	Upto 7	0
Mild	7-10	1
Moderate	10-15	2
Severe	Above 15	3

Walk Time

Table 9: Showing Walks Time

Walk time (for 25 feet)	Grade
>40 second or more	0
31-40 second	1
21-30 second	2
15-20 second	3

It is observed that P-Values for both the study groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 82.8% while effect observed in Group B was 66.7%.

Outcome of Therapies on Shotha (Swelling)

Table 11: Outcome of Therapies on Shotha (Swelling)

Swelling	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3.5	1	-3.992 ^a	0.000	75.4	Significant
Group B	3	1	-4.088 ^a	0.000	67.8	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 75.4% while effect observed in Group B was 67.8%.

Outcome of Therapies on Stabdhta (Stiffness)

Table 12: Outcome of Therapies on Stabdhta (Stiffness)

Stiffness	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3	0.5	-3.998 ^a	0.000	82.8	Significant
Group B	3	1	-4.008 ^a	0.000	63.9	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 82.8% while effect observed in Group B was 63.9%.

Outcome of Therapies on Jwara (Fever)

Table 13: Outcome of Therapies on Jwara (Fever)

Fever	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3	0	-4.042 ^a	0.000	86.8	Significant
Group B	3	1	-4.056 ^a	0.000	75.9	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 86.8% while effect observed in Group B was 75.9%.

Outcome of Therapies on Hemoglobin

Table 14: Outcome of Therapies on Hemoglobin

HB	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3	0.5	-4.058 ^a	0.000	81.1	Significant
Group B	3	1	-4.089 ^a	0.000	71.7	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 81.1% while effect observed in Group B was 71.7%.

Outcome of Therapies on ESR

Table 15: Outcome of Therapies on ESR

ESR	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3	0.5	-4.035 ^a	0.000	81.5	Significant
Group B	3	1	-4.072 ^a	0.000	64.7	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 81.5% while effect observed in Group B was 64.7%.

Outcome of Therapies on walking time

Table 16: Outcome of Therapies on walking time

Walking time	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3	0	-4.064 ^a	0.000	83.3	Significant
Group B	3	1	-4.134 ^a	0.000	68.6	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 83.3% while effect observed in Group B was 68.6%.

Outcome of Therapies on Grip strength

Table 17: Outcome of Therapies on Grip strength

Grip strength	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Group A	3	0	-4.053 ^a	0.000	87.3	Significant
Group B	3	1	-4.064 ^a	0.000	70.0	Significant

It is observed that P-Values for both the groups are <0.05 hence we conclude that the effect observed in both groups are significant. Further we can observe that, effect observed in Group A was 87.3% while effect observed in Group B was 70%.

Table 18: Effect of Therapies Comparison between the Groups

Parameter	Group	N	Mean Rank	Sum of Ranks	Mann Whitney U	P-Value
Pain	Group A	20	25.13	502.50	107.500	0.006
	Group B	20	15.88	317.50		
	Total	40				
Swelling	Group A	20	24.90	498.00	112.000	0.008
	Group B	20	16.10	322.00		
	Total	40				
Stiffness	Group A	20	25.30	506.00	104.000	0.005
	Group B	20	15.70	314.00		
	Total	40				
Fever	Group A	20	22.58	451.50	158.500	0.190
	Group B	20	18.43	368.50		
	Total	40				
HB	Group A	20	22.60	452.00	158.000	0.170
	Group B	20	18.40	368.00		
	Total	40				
ESR	Group A	20	24.95	499.00	111.000	0.005
	Group B	20	16.05	321.00		
	Total	40				
Walking Time	Group A	20	24.75	495.00	115.000	0.004
	Group B	20	16.25	325.00		
	Total	40				
Grip Strength	Group A	20	25.80	516.00	94.000	0.001
	Group B	20	15.20	304.00		
	Total	40				

For comparison between Group A and Group B we have used Mann Whitney U test. It is observed from above observation that P-Values for fever and Hb are >0.05 hence there is no significant difference in effect of Group A and Group B on fever and Hb. P-Values for

all other symptoms are less than 0.05 hence we conclude that there is significant difference in effect of Group A and Group B on, pain, swelling, stiffness, ESR, walking time and grip strength.

RESULT

DISCUSSION

In the condition of pain, *Khanda Shunthi* is found more effective than *Prasarini Avaleha* because pain is the cardinal symptom of *Vatadushti*. *Khanda shunthi* is made from *Ghrita*, It is having *Vatashamaka* property so *Khanda Sunthi* may be more effective in Painful condition. In the condition of *Shoth*, *Khndasunthi* is more effective than *Prasarni Avaleha* because in *Khanda shunthi*, *Shunthi* mixed in main *Dravya* and *Prakshepa dravya*. *Shunthi* is *Vatakapha shamak* and it shows anti-inflammatory action, *Sokhanda shunthi* may be more effective. In the condition of *Stabdhata*, *Khanada Shunthi* is more effective than *Prasarini avaleha*. In *Aamvata* stiffness present due to *Vata* and *Kapha*, *Khandashunthi* is having *Ghrita* and *Shunthi*. *Ghrita* is *Vatashamak* and *Shunthi* is *Vatakaphashamak* and *Amapachaka* so *Khanda shunthi* reduces the stiffness. Further we observed that, effect observed in Group A was 86.8% while effect observed in Group B was 75.9%. In the condition of fever, *Khanda Shunthi* is more effective than *Prasarni Avaleha*. In observational data, we found fever in all the patients. In *Aamvata*, fever present due to the *Aam dosha* and *Sama Pitta*. *Shunthi* is having *Ghrita*, *Khandasharkara* and *Shunthi* so its combination it subsides all *Dosha* and cure the fever. In the estimation of hemoglobin, *Khanda shunthi* is more effective than *Prasarni Avaleha*. In *Amavatarasa dusthi* is present due to this reason *Uttrotar-dhatu* i.e., from *Raktadhatu* to *Shukradhatu* do not form properly, *Khanda shunthi* has *Ghrita* and *Shunthi* as the ingredients. *Ghrita* is *Agnideepan* and *Shunthi* is *Aampachaka* so because of proper digestion and assimilation of *Ama* it forms pure *Rasa dhatu* so *Uttarotardhatu* (next *Dhatu*) will form appropriate. So, *Khanda shunthi* increases haemoglobin.

Further we can observe that, *Khanda sunthi* is more effective in pain, swelling and stiffness condition so it increase walking time, so it increase grip strength.

CONCLUSION

The present clinical study has been undertaken to evolve the treatment procedure for *Amavata* and to evaluate the clinical efficacy of *Khanda Shunthi* and *Prasarni Avaleha*. The study has revealed that in group A where patients of *Amavata* received *Khanda shunthi* 10 gram twice a day for 60 days showed reduction of pain 82.8%, swelling 75.4%, stiffness 82.80%, fever 86.80% and improved Hb 81.1%, ESR 81.5%, walking time 83.3% and grip strength 87.3%. The outcome is statistically significant. In group A where patients of *Amavata* received *Prasarni Avaleha* 10 gram twice a day for 60 days showed reduction of pain 66.7%, swelling 67.8%, stiffness 63.90%, fever 75.9% and improved Hb 71.1%, ESR 64.7%, walking time 68.6% and grip strength 70%. The outcome is statistically significant. Percent wise Group A treatment is more effective than Group B for all assessment criteria. From the aforesaid observations, it can be resolved that *Khanda Shunthi* because of its *Rasayana* and *Deepana* properties improves the nonspecific immunity against *Amavata*. Finally it can be concluded that *Amavata* patients have got significant results with these drugs. *Khanda sunthi* is more effective than *Prasarni Avaleha*. To draw final conclusions, the trial requires more clinical data.

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