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A randomised comparative clinical study to assess the efficacy of *Lavangadi Churna* over *Ajamodadya Churna* in the management of *Amavata*

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ABSTRACT

Background - *Amavata* is a disease, where involvement of *Ama* and *Vata* can be seen. Here formation of *Ama* and vitiation of *Vata* take place simultaneously by their respective causative factors. *Acharya Madhavakara* has described the *Amavata* first. This *Amavata* can be compared with Rheumatoid arthritis showing similarities in clinical features. **Objective -** To assess the effect of *Lavangadi churna* over *Ajamodadya Churna* in the management of Amavata. **Materials and Methods -** The sample size of the study consists of 40 patients of *Amavata*. and either sex of age group 20-60years. Patients were randomly selected and grouped into 2 groups namely Group A & Group B. Group A were given *Lavangadi churna* and Group B were given *Ajamodadya Churna*. The dosage of both the drug is 3gms twice in a day after food with lukewarm water. Follow up was fixed every 15th day i.e., 1st follow up on 15th day, 2nd follow up on 30th day, after treatment follow up on 45th day and duration of treatment was fixed 1 month. Patients were advised to follow *Pathyapathya* throughout the study. A special proforma was made to record the observation based on subjective and objective parameters. **Results and Conclusion -** Overall effect of the trial drug showed good response in both subjective parameters & objective parameters and Overall effect of the control drug showed good response in some parameters like Heaviness, Anorexia, Thirst, Fever. Hence trial dug supported research hypothesis. Intervention was cost effective, adaptable, and safe.

Key words: *Amavata, Ajamodadya Churna, Lavangadi Churna, Rheumatoid Arthritis, Stiffness.*

INTRODUCTION

Amavata is composed of two words, *Ama* and *Vata*, in which *Ama* is end product of incomplete digestion, due to impaired function of digestive fire. and it associates with aggravated *Vata* causes diseases named as *Amavata. Acharya Madhavakara* defined it as "*Amavata* is the disease where *Ama* and vitiated *Vata* along with *Kapha* settles in *Trika Sandhi* causing *Stiffness*, *Heaviness* etc. Here the vitiation of *Vata* and *Kapha* takes place simultaneously".[1]

Acharya Madhavakara was the first person to explain *Amavata* as a separate disease entity. Later *Acharya Chakrapani* has thoroughly described the treatment principle for *Amavata*. *Acharya Chakrapani* mentioned various formulations for *Amavata,* which are highly useful in treatment.

Later various *Acharyas* have explained etiology, symptoms, pathogenesis, types, treatment principles, complications, and do's & don'ts in detail. There is a detail explanation available regarding *Amavata* in various *Ayurvedic* literature.

He further tells, due to indulging in etiology, the vitiation of *Vata* and formation of *Ama* takes place simultaneously. Both these two factors move all over

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the body. and gets lodges in *Kapha* places & produces disease known as *Amavata.* and symptoms includes joint pain, stiffness, anorexia, heaviness, fever, indigestion etc.

Acharyas have described various measures like *Langhana, Swedana*, administration of *Tikta*, *Deepana, Katu Dravyas, Virechana*, different kinds of *Basti*, and numerous formulations for treatment of *Amavata.*

It can be corelated with Rheumatoid arthritis in modern aspect. Rheumatoid Arthritis is a chronic systemic inflammatory disorder that affects many tissues and organs including skin, blood vessels, heart, lungs and the muscles. But the disorder principally affects the joints, producing a non-suppurative proliferative synovitis that often progress to destruction of the articular cartilage and ankylosis of the affected joints.

The prevalence of RA worldwide is approximately 0.8% (0.3 to 2.1%) amongst the adult population. Whereas in India, the prevalence is 0.5% to 0.75% among adult population. the peak age of onset of RA is in the fourth and fifth decade of life with More than 75% patients developing disease between 30 and 50 years of age. As per the gender wise incidence, RA occurs more commonly in females than in males, with a ratio of 3:1.[2-4]

In modern medicine still researches are going on regarding, to find out exact etiology, pathogenesis, and treatment aspect. In modern medicine it is treated with NSAID's, Steroids, DMRAD's, and Immunosuppressants.

Ayurvedic literature describes many drugs in different formulations for treatment of *Amavata*. The drugs having the properties of *Amapachana*, *Deepana*, *Vatakaphahara*, *Lekhana*, *Shothahra*, *Srotoshodhana*, results in relieve from joint pain, swelling, stiffness, anorexia, fever and enhances digestive fire which helps in *Pachana* of *Ama.* For the treatment of *Amavata,* Drugs having the above-mentioned properties are must. So we have selected *Lavangadi Churna* and *Ajamodadya Churna* as described in *Bhaishajya Ratnavali* and *Sharangadhara Samhita Madhyama Khanda* respectively.[5,6] entitled it as "A randomised comparative clinical study to assess the efficacy of *Lavangadi Churna* over *Ajamodadya Churna* in the management of *Amavata*."

In this clinical trial, an attempt has been made to analyse the efficacy of *Lavangadi Churna* over *Ajamodadya Churna* by selecting 40 patients randomly and divided into two groups each containing 20 patients. For this clinical study Group A was assigned with *Lavangadi Churna* and Group B was assigned with *Ajamodadya Churna*.

Materials and Methods

Pharmaceutical Source

All the materials were collected from genuine local market. They are authenticated by the Dept. of *Dravyaguna,* BLDEA'S AVS Ayurveda Mahavidyalaya, Vijayapur. The formulations prepared as per the classical reference, in the BLDEA'S AVS Ayurveda Pharmacy attached to the Dept of *Rasashastra* and *Bhaishajya Kalpana* for the study.

Sample Source

A total of 44 patients were registered, with four being dropped out from the study, and total 40 being included in the research from the Dept of Kayachikitsa, BLDEA's AVS Ayurveda Mahavidyalaya Hospital and Research Centre. Patients were selected randomly divided in two groups Group A and Group B, each group contains 20 patients.

The Group A patients given with *Lavangadi Churna* and Group B patients given with *Ajamodadya Churna*. The parameters were noted before, during and after treatment, the results are observed with suitable statistical methods and further elaborated in this study.

Inclusion Criteria

a) Patients presenting with the classical signs and symptoms of *Amavata*.

b) Patients of either sex aged between 20 - 60 years.

c) Patients willing and able to participate in the study.

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Exclusion Criteria

a) Patients who are not willing for clinical study.

b) Patients suffering from acute systemic disorders as well as other known case if major illness like any type of Cancer, HIV, Gouty Arthritis, Syphilis, Tuberculosis, Gonococcal Infections etc.

c) Pregnant or Lactating Ladies.

Withdrawal Criteria

If the patient selected for this study, If patient not followed instructions properly, Then patient has considered as Dropout. If the symptoms of patient aggravated and will need any Emergency Medicine for relief, such patients has been dropped out from the study.

Investigations

- CBC
- ESR (Erythrocytes Sedimentation Rate)
- RA Test
- Radiological X-Ray of affected joints, if necessary
- CRP Test, if necessary.

Study Design

40 patients with *Amavata* has been taken for the study and randomly divided into 2 groups consisting of 20 patients in each group.

Group A

Sample Size : 20 Patients.

Formulation : *Lavangadi Churna*

Dosage : 3gm twice in a day.

Time of medicine intake : Post prandial medicine intake

Vehicle : Lukewarm water

Duration : 30 Days

Follow-Up : On every 15th day.

Group B

Sample Size : 20 Patients.

Formulation : *Ajamodadya Churna*.

Time of medicine intake : Post prandial medicine intake

Vehicle : Lukewarm water

Duration : 30 Days

Follow-Up : On every 15th day.

Parameter for Assessment:

Assessment has been done based on subjective and objective parameters. Before, during,

After the scheduled treatment with an interval of 15 days.

A) Subjective Parameters

1. Pain
2. Stiffness
3. Indigestion
4. Heaviness
5. Anorexia
6. Thirst
7. Sleep disturbance

B) Objective Parameters

1. Swelling
2. Fever
3. Loss of function
4. Grip Strength
5. Foot Pressure
6. Range of Movement
7. Functional Ability

Score Assessment Pattern

Subjective Parameters

1. Pain : Score

- No Pain : 0
- Mild (Does not interfere with most activities. Able to adopt to pain psychologically with medications or devices such as cushions) : 1
- Moderate (Interferes with many activities, requires lifestyle changes but patient remains independent. Unable to adopt pain) : 2

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- Severe (Unable to engage in normal activities. Patient is disabled and unable to function independently) : 3

2. Stiffness : Score

- No stiffness : 0
- Stiffness for 30 Min – 1 Hr : 1
- Stiffness for 1 Hr – 2Hr : 2
- Stiffness More than 2 Hr : 3
- Stiffness More than 2 Hr : 4

3. Indigestion : Score

- No indigestion : 0
- Heavy foods not digested properly : 1
- Delayed digestion of lighter foods : 2
- Impaired digestion of even lighter foods : 3

4. Heaviness : Score

- No feeling of heaviness : 0
- Occasional heaviness in body does usual work : 1
- Continuous heaviness in body but does usual work : 2
- Continuous heaviness which hampers the usual work : 3
- Unable to do any work due to heaviness : 4

5. Anorexia : Score

- Normal desire for food : 0
- Eating timely without much desire : 1
- Desire for food, little late, then normal time : 2
- Desire for food only after long intervals : 3
- No desire at all : 4

6. Thirst : Score

- Quantity of water intake 0-2 litres per day : 0
- Quantity of water intake > 2-3 litres per day : 1
- Quantity of water intake > 3-4 litres per day : 2
- Quantity of water intake > 4 litres per day : 3

7. Sleep disturbance : Score

- Sound sleep (6-8 Hr / Day) : 0
- Irregular sleep (6 – 7 Hr / Day) : 1
- Disturbed sleep due to pain (4 – 5 Hr / Day) : 2
- No sleep due to pain (< 4 Hr / Day) : 3

Objective Parameters

1. Swelling : Score

- No Swelling : 0
- Mild Swelling : 1
- Moderate Swelling : 2
- Severe Swelling : 3

2. Fever : Score

- Absence of fever : 0
- Fever symptom, without rise in temperature : 1
- Fever symptom, Temperature up to 100°F : 2
- Fever symptom, Temperature > 101°F : 3

3. Loss of function : Score

- Can perform personal daily work : 0
- Mild pain while doing daily personal work : 1
- Need others help : 2
- Dependent on others : 3

4. Grip Strength : Score

The patient's ability to compress the inflated ordinary sphygmomanometer cuff under standard conditions to assess the functional capacity of effected upper limb, both before, During and after treatment.

Grading is done as follows:

- 200 mm Hg or more : 0
- 200 to 120 mm Hg : 1
- 120 to 70 mm Hg : 2
- Under 70 mm Hg : 3

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5. Foot Pressure : Score

Foot pressure was recorded before, during and after treatment by the ability of the patient to press a weighing machine, to an objective view of functional capacity of lower limb.

Grading is as follows:

- 25 to 21 kg : 0
- 20 to 16 kg : 1
- 15 to 10kg : 2
- Less than 10 kg : 3

6. Range of Movement : Score

Measurement of range of joint movement using Goniometer before, during and after treatment.

Grading is as follows:

- 100° to 130° : 0
- 70° to 99° : 1
- 30° to 69° : 2
- 0 to 29° : 3

7. Functional Ability : Score

- Without any difficulty : 0
- With some difficulty : 1
- With much difficulty : 2
- Unable to do : 3

Statistical Analysis

The obtained data was analyzed statistically with Chi square test, Friedman test, Mann Whitney U test and Wilcoxon signed rank test.

Overall Assessment

- Good Response - If the overall improvement is >75%
- Moderate Response - If the overall improvement is greater than or equal to 50% but <75%
- Poor Response - If the overall improvement is less than 50%

OBSERVATIONS

The observations of the present study in the age category reveals that 50% of patients age group is between 30 to 50years, 35% of patients age group is above 50years. In Group A it was observed that, 45% patients' occupation was house work, 25% patients' occupation was office work. In Group B, 40% patients' occupation was house work, both field work and office work contains 25% patients. It was observed in this study, majority of the patients in Group A and Group B belongs to *Madhyama Koshta* i.e., 70% & 75% respectively.70% of the patients in Group A have chronicity of < 1year, and while in Group B 60% of the patients have chronicity of < 1 year. Both in Group A and Group B 45% patients' onset were gradual. 55% & 50% patients' onset were sudden in Group A and Group B respectively. In Group A 55% patients were belonged to *Vata-Pitta Prakruti* and In Group B 60% patients belonged to *Vata-Pitta Prakruti.* 85% patients in Group A and 95% patients in group B were having *Madhyama Sara*. Majority of the patients in Group A & Group B were having *Madhyama Samhanana* i.e., 80% and 70% respectively. 95% & 75% patients in Group A and Group B were having *Madhyama Pramana*. In Group A, 50% & in Group B, 80% patients were having *Madhyama Satmya*. In Group A, 65% & in Group B patients were having *Madhyama Satwa.* In Group A, 70% & in Group B 80% patients were having *Madhyama Ahara Shakti*. In Group A 65% & in Group B 40% patients were having *Madhyama Vyayama Shakti*.

Majority of the patients in both the groups were having pain, Anorexia, indigestion, heaviness. Majority of the patients in Group A & Group B were not having thirst i.e., 80% & 70% respectively. In Group A 60% & in Group B 40% patients were having sleep disturbance. 65% patients in both the groups were having Swelling and fever. 80% patients in both the groups were having loss of function and deterioration of functional ability. 60% patients were not having reduced grip strength and foot pressure.

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RESULTS

Table 1: Effect of *Lavangadi Churna* on Group A.

Parameters	Before Treatment		After treatment follow up		Mean Diff	In %	Wilcoxon signed rank test	P value
	Mean	SD	Mean	SD				
Pain	1.45	0.510	0.00	0.000	1.45	100%	4.041	0.0001*
Stiffness	1.45	0.605	0.05	0.224	1.4	97%	4.053	0.0001*
Indigestion	1.05	0.686	0.00	0.000	1.05	100%	3.666	0.0001*
Heaviness	0.85	0.587	0.00	0.000	0.85	100%	3.690	0.0001*
Anorexia	1.15	0.489	0.00	0.000	1.15	100%	4.300	0.0001*
Thirst	0.20	0.410	0.00	0.000	0.20	100%	2.000	0.046*
Sleep Disturbance	0.65	0.587	0.00	0.000	0.65	100%	3.357	0.01*
Swelling	0.75	0.639	0.00	0.000	0.75	100%	3.419	0.01*
Fever	0.55	0.759	0.00	0.000	0.55	100%	3.419	0.01*
Loss of Function	0.85	0.366	0.05	0.224	0.8	94%	2.598	0.009*
Grip-Strength	0.45	0.510	0.00	0.000	0.45	100%	4.000	0.0001*
Foot-Pressure	0.25	0.444	0.00	0.000	0.25	100%	3.000	0.003*
Range of Movement	0.30	0.470	0.00	0.000	0.30	100%	2.236	0.025*
Functional Ability	0.85	0.366	0.00	0.000	0.85	100%	2.449	0.014*

* Statistically significant

Graph 1: Showing effect of *Lavangadi Churna* on group A.

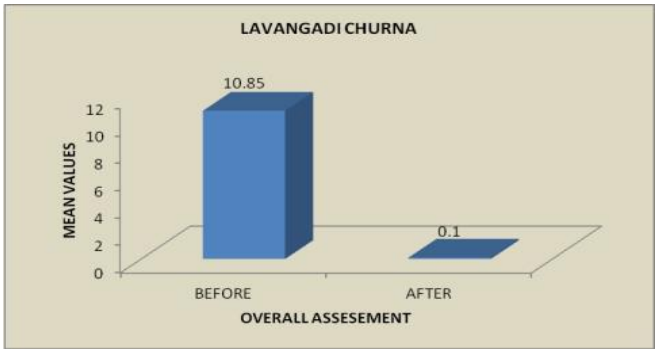

Table 2: Effect of *Ajamodadya Churna* on Group B.

Parameters	Before treatment		After treatment fallow up		Mean Diff	In %	Wilcoxon signed ranks test	P value
	Mean	SD	Mean	SD				
Pain	1.45	0.510	0.60	0.681	0.85	59%	3.690	0.0001*
Stiffness	1.45	0.605	0.70	0.865	0.75	52%	3.095	0.002*
Indigestion	1.05	0.759	0.15	0489	0.9	86%	3.819	0.0001*
Heaviness	0.90	0.553	0.25	0.550	0.65	72%	3.606	0.0001*
Anorexia	0.90	0.641	0.15	0.489	0.75	83%	3.873	0.0001*
Thirst	0.35	0.587	0.05	0.224	0.3	86%	2.449	0.014*
Sleep Disturbance	0.50	0.688	0.20	0.410	0.3	60%	2.121	0.034*

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Swelling	0.65	0.587	0.30	0.470	0.35	54 %	2.646	0.008*
Fever	0.50	0.761	0.00	.000	0.50	100%	2.428	0.015*
Loss of Function	0.95	0.224	0.45	0.510	0.44	46 %	3.162	0.002*
Grip-Strength	0.60	0.598	0.55	0.605	0.05	8.3 %	1.000	0.317
Foot-Pressure	0.35	0.489	0.30	0.470	0.05	14 %	1.000	0.317
Range of Movement	0.35	0.489	0.30	0.470	0.05	14 %	1.000	0.317
Functional Ability	0.95	0.224	0.45	0.510	0.5	53 %	3.162	0.002*

* Statistically significant

Graph 2: Effect of *Ajamodadya Churna* on Group B.

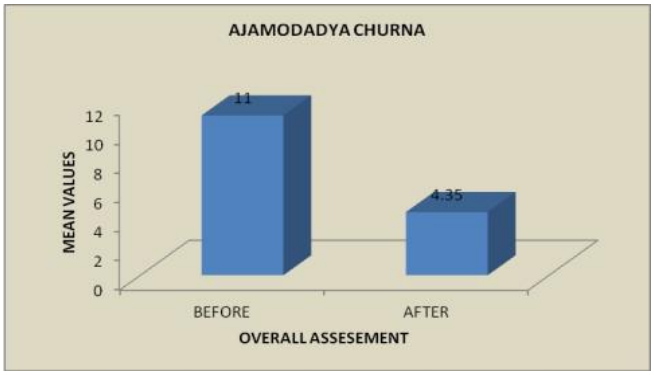


Table 3: Overall result of all parameters in Group A.

Parameters	BT		ATFU		Mean Diff	In %	Wilcoxon signed rank test	P value
	Mean	SD	Mean	SD				
Total Score	10.85	3.249	0.10	0.308	10.75	99 %	3.928	0.0001*

*: Statistically highly significant

Table 4: Overall result of all parameters in Group B.

Parameters	BT		ATFU		Mean Diff	In %	Wilcoxon signed ranks test	P value
	Mean	SD	Mean	SD				
Total Score	11.00	4.713	4.35	5.194	6.65	60 %	3.924	0.0001*

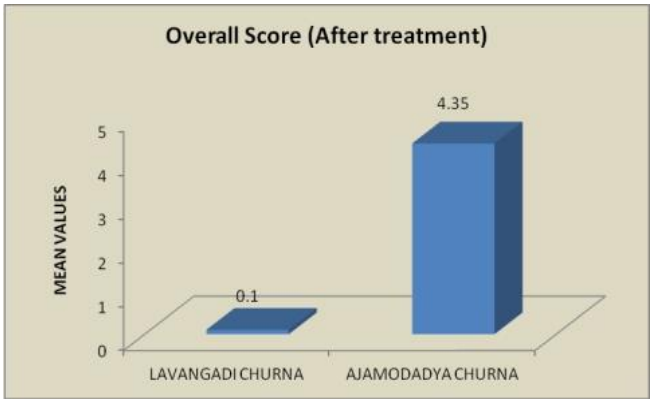
*: Statistically highly significant

Table 5: Comparison of overall result of all parameters between *Lavangadi Churna* and *Ajamodadya Churna*.

Parameters	Lavangadi Churna		Ajamodadya Churna		Mean Diff	In %	Mann Whitney U Test	P value
	Mean	SD	Mean	SD				
Total Score	0.1000	0.308	4.35	5.194	4.25	98 %	67.00	0.0001*

*: Statistically highly significant

Graph 3: Showing overall score.



DISCUSSION

Pain usually seen in *Amavata* due to aggravation of *Vata*, usually aggravation of *Vata* occurs either due *to* obstruction and depletion of dhatus.[7] In this present context *Vata* vitiation is due to obstruction of *Vata* by *Ama*. The majority of the drugs in this trial drugs are

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having properties *of Katurasa*, *Ushna Virya*, *Katu Vipaka* and *Vata Kaphahara*. Hence the trial does the *Deepana* and *Ama Pachana,* this in turn destroys the obstruction of channels caused by *Ama.* Once this process occurs in the body *Vata* will have normal movement. Present study of trial drug reveals that by doing *Agni Deepana* and *Ama Pachana* it will yield good response in subjective criterion like Pain.

Stiffness in *Amavata* is mainly due to presence of *Ama* & involvement of vitiated *Kapha Vata Doshas*. The drugs in this formulation contains *Katu Rasa*, *Ushna Virya*, *Katu Vipaka* are *Danti, Yavani, Lavanga, Vacha, Chavya, Chitraka, Ajamoda*. And these drugs are having functions *like Deepana*, *Pachana, Vata-Kaphahara*. By these properties they do *Ama Pachana*, *Agni Deepana* and controls the involved vitiated *Vata Kapha Doshas*. Coldness property of vitiated *Vata Kapha Doshas* and unctuousness of *Ama* are alleviated by sharp, hot, dry properties of trial drug. Hence the trail drug shown good response in alleviating the stiffness.

The indigestion occurs due to *Ama* or vice versa. Indigestion is important symptom of *Ama*. The ingredients of the trial drugs contain *Katu Rasa, Ushna Virya, Katu Vipaka* are *Danti, Yavani, Lavanga, Vacha, Chavya, Chitraka, Ajamoda.* The *Katu Rasa* consider to be *Deepaniya*, and majority of the drugs having *Deepana* as a main function. By virtue of above said properties the trial drug efficiently acts on indigestion.

Heaviness and anorexia usually seen in *Amavata* due to presence of *Ama* and involvement of vitiated *Kapha*. The trial drug is having properties like *Deepana*, *Ama Pachana, Kaphahara*. Hence by alleviating the *Ama* & normalizing vitiated *Kapha,* it reduces the heaviness and anorexia.

Acharya Charaka told various types of thirst in *Chikitsasthana* 22nd chapter namely *Vataja*, *Pittaja*, *Amaja*, *Kshayaja*, *Upsargaja Trishna*.[8] In this context we should consider *Amaja Trishna*. The trial drug does elimination of *Ama* by virtue of *Deepana, Ama Pachana* properties significantly reduces the thirst.

The sleep disturbance usually seen in *Amavata* either may be due to involvement of vitiated *Vata* or due to presence of pain, stiffness, etc. and also due to presence of *Kapha*, patients used to sleep more at day time that leads to sleep disturbance at night time. This trial drug having property *Vatahara*, *Ama pachana* & it reduces the symptoms like pain, stiffness etc. by above said properties. Thus, the trial drug significantly effective in alleviating the sleep disturbance.

Acharya Charaka explained in *Chikitsasthana* 12th chapter, the vitiated *Kapha, Rakta*, & *Pitta* enter into the external channels and does the obstruction that leads to *Vata* vitiation. This causes the manifestation of swelling.[9] The trail drug *Lavangadi Churna* being *Vata Kaphahara* property removes the obstruction. and the trial drug contains *Gokshura* as one of the ingredients, *Gokshura* is having anti-inflammatory action. So, virtue of these properties it significantly pacifies the swelling.

Fever in *Amavata* is due to dislodgement of digestive fire from its normal place. In this context *Ama* does obstruction to the *doshas* leading to displacement of digestive fire results in fever. This trial drug by virtue of *Deepana, Amapachana* does the elimination of *Ama* and alleviates fever.

Grip strength is the combined effort of joints like DIP, mcp, wrist and muscular strength and Foot pressure is the combined effort of joints of foot, leg and muscular strength. The trial drug significantly reduces the symptoms like joint pain, stiffness, swelling. This results in significant action on improving the grip strength and foot pressure.

Range of movement of joints and functional ability diminishes due to presence of swelling stiffness, pain in the joints. Efficacy of trial drug pain, stiffness, swelling results in improvement of range of movement of joints and functional ability.

CONCLUSION

Ama, vitiated *Vata* and decreased digestive fire plays very important role in manifestation of *Amavata*. The etiological factors explained in ancient literature for *Amavata*, were found to cause *Amavata* in patients of present study also. The trial drug *Lavangadi Churna* showed good response both in subjective and objective parameters which are statistically significant. The control drug *Ajamodadya Churna* showed good

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response in some parameters like heaviness, anorexia, thirst, fever and showed moderate response in some parameters like pain, swelling, stiffness, sleep disturbance & in functional ability. Showed poor response in some parameters like Grip strength, Foot pressure, Functional ability. After completion of the intervention, the trial drug supported Research Hypothesis i.e., *Lavangadi Churna* may have better results than *Ajamodadya Churna* in *Amavata*. The trial drug is most effective in *Samavastha* of the disease with *Vata* and *Kapha* predominance and should be used vigilantly in case of predominance of *Pitta Dosha.* The formulation is cheap, cost effective in the management of *Amavata.*

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