



ORIGINAL RESEARCH ARTICLE

EVALUATION OF THE EFFECT OF AN AYURVEDIC DIETARY FORMULATION (*PANCHAKOLASIDDHAYAVAGU*) IN REDUCING THE DISEASE ACTIVITY SCORE (DAS28 USING C-REACTIVE PROTEIN) AMONG *AMAVATA* PATIENTS

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Abstract

Background: *Amavata*, is one among the multiple joint disorders explained in Ayurvedic classics. Its pathology is explained to be beginning with the sluggish functioning of the bio fire (*agni*) or the digestive capacity. The disease is having high prevalence rate and is of crippling nature. Practically there is no effective proven intervention in popular practice to break the chains in the pathogenesis by correcting the bio-fire. Hence it was a high time to develop such an intervention with a therapeutic diet restricting all other medicine and food to check the pathogenesis and thereby the disease activity. **Objective:** The study attempted to evaluate effect of an Ayurvedic dietary formulation, *Panchakolasiddhayavagu* in reducing the disease activity by using the Disease Activity Score (DAS 28) using CRP, among *amavata* patients. **Materials and Methods:** In this uncontrolled clinical trial 20 participants were selected. Intervention was till the attainment of proper digestive capacity, the optimum functioning of bio fire or maximum up to 10 days. *Panchakolasiddhayavagu* prepared as per the classical reference was given in morning and evening restricting all other food and medicine. Pain was assessed daily using Numerical Rating Scale. Disease activity score was used to assess the symptomatic relief. **Results:** There was highly significant reduction in pain ($p < 0.001$) and significant reduction in disease activity ($p < 0.001$). The intervention shows significant results in reducing the CRP levels ($p < 0.05$). **Conclusion:** Administration of the Ayurvedic dietary preparation, *panchakolasiddhayavagu* was highly effective in reducing the disease activity score DAS28. It was highly effective in reducing the pain and maximum significant change is observed between day 7 and day 8. It also helped to reduce the CRP levels significantly.

Key Words: *Panchakolasiddhayavagu*, Disease Activity Score, DAS28, *Amavata*, *rheumatoid arthritis*

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INTRODUCTION

Ayurveda refers *agnimandya* (sluggish bio fire) as the root cause of all ailments.^[1] The maintenance of health and the wellbeing; and the sustenance and the dissolution of body of every individual depend upon the *agni*.^[2] *Agnimandya* further leads the genesis of *ama*, the partially digested, faulty formed rasa, i.e. the first end product of the digestion.^[3] This *ama* is creating the obstruction of the normal functioning of the body, reduces the strength of the affected individual and the proper functioning of the vital elements become impaired.^[4] The resultant diseases originating from *ama* are based on the site of the body part where it gets localized and the associated *dosha*.^[5] The procedures explained to conquer *ama* is summarized as *langhana* (slimming therapy, or emaciation therapy) with warm *peya* (rice gruel), *laghuanna* (easily digestible light food), *rukshaodana* (dry food which is not oily) or *tiktayusha* (soups with bitter drugs) followed by *niruha* (enema), *svedana* (sudation), *pachana* (digest out the waste matter) and *urdhvaadhasodhana* (body purification measures such as emesis and purgation).^[6] In this condition medication is absolutely contraindicated.^[7-9] Food, activities and emotional disturbances are the contributory factors of the genesis of *ama*.^[10] In the present era practices like unwholesome food, regime; hectic schedules

and stress most of the people are at threat. In *amavata* the profuse *ama* has a special inclination towards the joints which are one among the seats of *kapha*, and leads to the crippling multiple joint involved rheumatologic ailments like rheumatoid arthritis, post viral arthralgia etc.^[11] While considering the debilitating nature of the disease conditions absolute fasting is contraindicated.^[12] Ancient scholars consider diet (*ahara*) as the supreme medicine.^[13] If people follow *pathyahara* (wholesome diet) there will be no need of giving further medication; and if people do not follow the *pathyahara* the mere medication is in vein.^[14] Therapeutic diet is explained as the controlled and specific utilisation of the food article as a beneficiary tool to tackle the diseased conditions.^[15] *Aharakalpanas* (dietary preparations) are explained in all the classical texts as an integral part to maintain the health and to restore health, i.e. both preventive as well as therapeutic aspects are emphasized. This study was an attempt to develop a safe, cost effective Ayurvedic therapeutic dietary preparation to address the *agnimandya*, *ama* which in turn results in the reduction of disease activity up to the possible extent. Three *doshas* i.e. *vata*, *pitta* and *kapha* will be simultaneously vitiated (*samasannipatikadoshadushti*) in *amavata*. It is a crucial pathological state where the *dosha* vitiation (*doshadushti*) is similar to the toxic

element (*visha*) or it is capable to produce toxic substances. In this stage the immune system will be in a compromised phase.^[16] *Langhana* is indicated as the first option in the treatment of *amavata*.^[17-19]

Panchakolasiddhapana and *anna* is specially indicated in *amavata* treatment.^[20] From these available guidelines we can conclude that *langhana* is the first thing to be done to pacify the *ama* and further to check the chain of events in the pathogenesis. Since the stage of the disease which is associated with *ama* (*sama* stage) is immune compromised and the strength (*bala*) of the patient is poor, absolute *langhana* is not advisable. Practically relative *langhana* will be better. In *amavata* due the compromised function of *agni*, the first end product of the digestion i.e. *rasadhatu* is not properly formed both quantitatively and qualitatively and further the subsequent tissue (*uttarottaradhatu*) formation is also impaired, i.e. the individual will be in a malnourished stage. *Langhana* promotes *agni* and exhaust *ama* leading in turn to the cessation of the chain of events in the pathogenesis.^[12]

Acharya Charaka gives due importance to the rice gruel preparation *yavagu*, which is mentioned as a part of post-operative diet in purification measures and as therapeutic diet in case of various pathological conditions.^[21] The properties of *panchakola* and the properties of

panchakolasiddhayavagu are opposite to that of *ama* and both helps to augment the *agni* and digest the *ama*^[21, 22]

In the context of *amavata* the administration of *panchakolasiddhayavagu* was aiming the basic treatment principle of *samprativighatana* i.e. breaking the chain of events in the pathogenesis. This in turn results in the reversal of the mechanism of disease manifestation.^[12]

MATERIALS AND METHODS

The study was done as an uncontrolled clinical trial. The participants were selected from the Vaidyaratnam P S Varier Ayurveda College Hospital, Kottakkal, Kerala.

Ethics: Informed written consent was obtained in document form after being informed regarding the study, they were involved in. Details about the intervention and duration of the study were explained. Those who were willing, the consent obtained from participants, only included in the study. They were given the freedom to quit from the study at any part of it at their own will.

The study synopsis along with questionnaire was placed before Institutional Ethics Committee of Vaidyaratnam P S Varier Ayurveda College, Kottakkal. After the various levels of scrutiny and subsequent modification based on their recommendations, the final acceptance was gained and Ethical clearance was obtained for the study.

Study design: Uncontrolled clinical trial

Study Population: The population of Amavata patients from Northern districts of Kerala, those who utilize the facility of VPSV Ayurveda College facilities, who were representative of target population, participated in the study.

Sampling: Sampling is done by the convenient sampling method from the amavata patients who attend the VPSV Ayurveda College Hospital.

Sample size: Before starting the study a newspaper announcement was given and screening of 52 participants was done in OPD, Vaidyaratnam P.S. Varier Ayurveda College Hospital. Among the screened participants 20 participants satisfying the inclusion criteria and willing to give informed written consent were included in the study.

Study setting: The study was carried out in Vaidyaratnam P.S. Varier Ayurveda College Hospital, Kottakkal, Kerala, South India, from June 2015 to March 2016.

Selection and Description of Participants:

Inclusion criteria: Participants in the age group 18- 50 of either sex, having multiple joint pain with any four of the following confirmatory symptoms and more than two of associated symptoms, were included after getting an informed written consent: Pain all over the body (*Angamarda*), impaired taste perception (*Aruchi*), excessive thirst (*Trishna*), feeling laziness to do day to day activities (*Alasyam*),

heaviness of the body (*Gouravam*), feverishness (*Jwara*), improper digestive activity (*Apaka*), generalized swelling over the body (*Anganamsunata*), general fatigue (*Utsahahani*), constipation (*Vidvibandhata*) and excessive salivation (*Praseka*) were considered as the confirmatory symptoms.

Increased urine output (*Bahumutrata*), disturbed sleep (*Nidraviparyaya*), excruciating pain like scorpion bite (*Vrischikadamsavatvedana*), poor appetite (*Agnidourbalyam*), burning sensation (*Daha*), discomfort in chest (*Hridgraham*), gaseous accumulation with resonance (*Antrakujanam*), colicky pain in abdomen (*Kukshisula*) and tastelessness (*Vairasyam*) were considered as the associated symptoms.

Exclusion criteria: Patients with chronicity more than 5 years, those who were pregnant or lactating women were excluded. Those who had major systemic illness like uncontrolled hyperglycaemia with complications and malignant hypertension were excluded.

Selection of Drugs: *Panchakola* purchased from a GMP certified drug manufacturing company.

Trial drug details:

Panchakola is the drug utilized for the intervention. The ingredients are enlisted below in detail.^[21]

Table 1. Composition of Panchakola

Sl. No.	Drug	Latin Name	Family	Parts Used	Ratio
1	<i>Pippali</i>	Piper longum.	Piperaceae	Fruits	1 part
2	<i>Pippalimoola</i>	Piper longum.	Piperaceae	Root	1 part
3	<i>Chavya</i>	Piper chaba.	Piperaceae	Fruit	1 part
4	<i>Chitraka</i>	Plumbago zeylanica	Plumbaginaceae	Fruit	1 part
5	<i>Nagara</i>	Zingiber officinalis.	Zingiberaceae	Rhizome	1 part

Method of Preparation of panchakolasiddhayavagu: Panchakolakwatha was prepared before one day taking 50g Panchakola boiling in 3200 ml water, reduced to 1600ml. Kwatha was filtered and 250g rice was added to the kwatha and gruel was prepared. Kwatha prepared with Panchakola in water (1:64 ratio, reduced to half), Yavagu prepared with the kwatha and rice (6:1).

Intervention given: For the selected participants the medicated rice gruel prepared of panchakola (panchakolasiddhayavagu) was given, prepared as per classical reference, till the attainment of proper digestive capacity, the optimum functioning of bio-fire or maximum up to 10 days. Rice gruel prepared with 125g rice, cooked in the panchakolakwatha (decoction) made of 50g of panchakola was given twice daily. Time of administration was fixed as morning 6.30 to 7.30AM and evening, 6.30 to 7.30PM.

Assessment and Data collection: The patient data including both the socio demographic details and other relevant clinical data were collected and documented in the suitably designed data collection form designed as per the need of the study. Disease activity score DAS28 was used to assess the symptomatic changes. Agni and Pain were also assessed daily using numerical rating scale to assess the symptomatic changes. Hematological parameter –CRP was measured before and after.

Data analysis: Data was checked, analyzed and presented with the help of tables, graphs. Mean standard deviation. Paired t test was used to assess effect of intervention DAS28 and CRP. Statistical analysis was done by using Microsoft Office 2007 Excel, Graphpad InStat version 3, and IBM SPSS Statistics version 16.

During the course of intervention or during the follow up period any adverse

events or complications were not reported. After the completion of the study, those participants who need further treatment or follow up were directed to the OPD or IPD of the VPSV Ayurveda College Hospital.

RESULTS

Characteristics of study participants

The participants selected for the study had a mean age of 42.05. The study included 80% female and 20% male participants. Only 5% participants belong to very poor class. 15% belongs to poor, 30% belongs to lower middle and 50% belongs to the middle class. All the participants were following mixed dietary

pattern. 95% participants had poor appetite. Only 5% claimed to have moderate appetite.

Assessment of pain

To assess the variance due to intervention between individual days' (from 0th day to 11th day) mean values of pain numerical rating score, repeated measure ANOVA was carried out. (Table 2). The pain numerical rating scale between individual days were statistically different, F = 181.33, p<0.001. Hence post hoc analysis with Tukey – Kramer multiple comparison test was done between the daily assessments (Table 3).

Table 2. Variance due to intervention in pain score – RM ANOVA test

Source of variation	Df	Sum of squares	Mean square	F value	P value
<i>Treatment (between columns)</i>	11	1559.8	141.80	181.33	P < 0.001
<i>Individual (between rows)</i>	19	484.71	25.51		
<i>Random (residual)</i>	209	163.44	0.78		
<i>Total</i>	239	2208.0			

Table 3. Multiple comparison in pain numerical rating score of consecutive days - Tukey-Kramer Multiple Comparisons test

Comparison	Mean Difference	q	P value
DAY 0 vs DAY 1	0.000	0.000	P>0.05
DAY 1 vs DAY 2	0.6000	3.034	P>0.05

DAY 2 vs DAY 3	0.9000	4.552	P>0.05
DAY 3 vs DAY 4	1.050	5.310	P<0.05
DAY 4 vs DAY 5	0.6500	3.287	P>0.05
DAY 5 vs DAY 6	0.6000	3.034	P>0.05
DAY 6 vs DAY 7	0.7000	3.540	P>0.05
DAY 7 vs DAY 8	0.5000	2.529	P>0.05
DAY 8 vs DAY 9	2.000	10.114	P<0.001
DAY 9 vs DAY 10	0.000	0.000	P>0.05
DAY 10 vs DAY 11	0.000	0.000	P>0.05

Assessment of changes in C reactive protein difference 7.79(26.59% decrease). This mean CRP was found to be decreased from 29.28 to 21.49 after the intervention with a mean difference was found to be statistically significant with t = 2.670, p<0.05 (Table 4).

Table 4. Effect of intervention on C R P – Paired ‘t’ test

	Mean	SD	%	‘t’ value	P value
BT	6.56	1.16	52.53	18.63	P<0.001
AT	3.11	1.35			

Assessment of Disease Activity Score, Disease Activity Score in 28 Joints – DAS 28 with CRP difference 3.45 (52.53% reduction). This mean Disease activity score was reduced from 6.56 to 3.11 after the intervention with a mean difference was found to be statistically significant with t = 18.63, p<0.001(Table 5)

Table 5. Effect of intervention on DAS with CRP– Paired ‘t’ test

	Mean	SD	%	‘t’ value	P value
BT	6.56	1.16	52.53	18.63	P<0.001
AT	3.11	1.35			

DISCUSSION

The participants had a mean age of 42.05 years. Among the participants, major share i.e. 70%, belongs to 41 – 50 years groups. This is consistent with the previous studies in which 76% participants belongs to age group 30 – 60 where in the present study upper age limit

was fixed as 50 years. [23] The clinical presentation of *amavata* closely mimics with the special variety of rheumatologic disorders called rheumatoid arthritis (R.A.), in accordance with their similarities on clinical features, like pain, swelling, stiffness, fever, redness, general debility are almost identical.

The disease R.A. is chronic in nature and affects mostly the middle aged group. The onset of disease is frequent during 4th and 5th decade of life with 80% of participants developing the disease between 30-65 years of age.^[24]

In this study 80% participants were females. Community prevalence study reports that female are more sufferers of *amavata* than male and 3:1 is the ratio of occurrence between them.^[25] The incidence of RA is typically two to three times higher in women than men.^[24] Moreover female population is more in North Malabar region from where the participants are coming from.^[26]

Only 5% participants belong to very poor class. 15% belongs to poor, 30% belongs to lower middle and 50% belongs to the middle class. This data represents the economic class who utilise the facility of Ayurveda College OPD. On the other hand few studies suggest that increased urbanization has seen the rise of the middle classes and it is predominantly the diet and lifestyle preferences of this group that mark a change with the past.^[27] These changing dietary habits may alter the proper functioning of bio fire. Due to the practice of incompatible food, lack of physical activity, exertion just after food intake and stress and may lead to hypo-functioning of bio-fire. As a result the ingested food is not digested to the proper end products and *ama* is generated.^[28]

All the participants were following mixed dietary pattern. Injudicious intake of more than one type of food which are incompatible as usual in case of fast foods, may give rise every chance of *agnimandya*, *rasadhatudushti* and the further formation of *ama*.

All the participants *agni* was in *mandavastha*. This may lead to the impaired formation of the first *dhatu*.^[3] This faulty formed *rasadhatu* known as *ama* is the basic element in the pathology of the present disease.^[11] *Mandagni* is mentioned as the basic cause of all disease which may manifest as different disease as per the site of the pathogenesis.^[1]

Pain was assessed daily based on a numerical rating scale. To assess the variance due to intervention between individual days' (from 0th day to 11th day) mean values of pain numerical rating score, repeated measure ANOVA was carried out. The pain numerical rating scale between individual days were statistically different and the test was statistically highly significant with $p < 0.001$. On post hoc analysis with Tukey – Kramer multiple comparison test it was observed that the changes between day 3 and day 4; and between day 8 and day 9 were found to be statistically significant with $p < 0.05$ and $p < 0.001$ respectively. The changes between all other consecutive days were found to be statistically insignificant. This implies there was not that much changes in the initial 3 days

and the first significant change was observed between day 3 and day 4. The maximum significant change is observed between day 8 and day 9. If we consider the changes between day 1 with the succeeding days day 4 onwards there is highly significant changes at $p < 0.001$, till the 7th day. But while comparing the consecutive days the statistically significant changes are confined to the two levels explained earlier.

The CRP was found to be decreased from 29.28 to 21.49 after the intervention with a mean difference 7.79(26.59% decrease). This mean difference was found to be statistically significant with $p < 0.05$. CRP is found to be more sensitive than ESR and the change was significant. In case of CRP 3 to 7 days are enough to reach the normalcy.^[29,30]

Disease activity score is used to guide treatment decisions and describe disease activity. DAS28 can be calculated either by using the ESR or CRP values. Since CRP was found to be more sensitive it was calculated based on the CRP values. DAS28 was reduced from 6.56 to 3.11 after the intervention with a mean difference 3.45, i.e. 52.53% reduction. This mean difference was found to be statistically significant with $p < 0.001$. Clinically it means that the initial disease activity was high and it came down to moderate level.

Panchakola is the drug utilized for the preparation of this therapeutic diet used for

intervention. The property of *panchakola* is enlisted as *agnideepana* (carminative), *amapachana* (digestive) and *sulahara* (analgesic). *Pippali* (Piper longum Linn.), *pippalimula* (root of the Piper longum Linn.), *chavya* (Piper chaba Hunter), *chitraka* (Plumbago zeylanica Linn.) and *nagara* (Zingiber officinale) are the ingredients of *panchakola*.^[31] Application of *deepaneeya* drug is for stimulation and increase of digestive fire while *pachaneeya* drug is useful to address indigestion. The analgesic (*sulaghna*) and *deepaneeya* effect of *panchakolasiddhayavagu* is already mentioned in classics.^[32]

Disease Activity Score in 28 Joints using C-reactive protein (CRP) is a widely used scoring system to evaluate treatment efficacy and is useful in monitoring disease activity of RA patients in daily practice.^[33-35]

Disease Activity Score in 28 Joints is helpful to clinicians to make a decision regarding the further management of the disease condition with disease-modifying anti-rheumatic drugs (DMARDs).^[36] Miscalculation of DAS28 score results in incorrect patient assessment and treatment plan.^[37] CRP is more precise tool in assessing inflammation since it is an acute-phase reactant. It increases within 4 to 6 hours of inflammation or acute tissue injury.^[38] It is already proven that Ayurvedic drugs such as *erandatailam*, *hingutrigunatailam* and

panchakolachurnam have definite role to play in modifying the disease *amavata*, similar to the disease modifying anti rheumatic drugs (DMARD).^[32]

Laghu (lightness) *guna* (property) helps to attain *langhana*, *teekshna* (quick/penetrating) *guna* facilitates *paka* (transformation), *ruksha* (dryness) *guna* causes drying up and reduces the swelling all over the body and especially at *sandhis*. It is already reported that *panchakolasiddhayavagu* is helping the attainment of *samyaklanghana* and thereby helps to reduce the general symptoms of inflammation like feverishness, heaviness of body and pain all over the body.^[39]

CONCLUSIONS

In the present study the objective was to evaluate effect of *panchakolasiddhayavagu* in reducing the disease activity by using the Disease Activity Score (DAS 28) using CRP, among *amavata* patients. DAS 28 value and CRP value were assessed before and after the treatment. Pain was assessed daily. Paired 't' test was the statistical test chosen for before and after comparison. In case of daily measured parameter, pain, to assess the difference between consecutive days, repeated measures ANOVA was done. Post hoc analysis was done with Tukey-Kramer Multiple Comparisons test.

Panchakola was already known to have *sulahara* property. The specific diet indicated

in the context of *amavata*, i.e. *Panchakolasiddhayavagu* was found to be highly effective in reducing the disease activity score DAS28 among the *amavata* patients. The evaluation of the pain assessed through numerical rating scale shows that *Panchakolasiddhayavagu* was highly effective in reducing the pain. In case of pain assessment, maximum significant change was observed between day 7 and day 8. *Panchakolasiddhayavagu* reduced the CRP levels, which is more sensitive tool in case of inflammatory conditions, significantly. A simple dietary formulation itself is highly effective in reducing the disease activities of *amavata*, since it breaks the chain of events in the pathogenesis of the disease. From these observations we can conclude the role of diet in the management *amavata*.

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