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Clinical Study to evaluate efficacy of *Panchamuladi Kaal Basti* in the management of *Amavata* w.r.t. Rheumatoid Arthritis

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ABSTRACT

Rheumatoid Arthritis is a chronic autoimmune inflammatory disease that causes to pain, stiffness and swelling of the joints. It affects different parts of the body, mainly effects the joints. *Amavata* (Rheumatoid Arthritis) has been a challenging problem to the medical field. Various treatment protocols are applied in this disease with partial success. In present clinical study, 30 patients of clinically proven *Amavata* (Rheumatoid Arthritis) were treated with *Panchamuladi Kaal Basti* to evaluate its efficacy. *Panchamuladi Kaal Basti* contains *Kwatha Dravyas* viz. *Bilwa*, *Agnimantha*, *Syonaka*, *Patala*, *Kantakari* etc. with other *Kalka* and *Prakshepa Dravyas*. Ayurvediya *Nidanadi* parameters and American Rheumatism Association guidelines for Rheumatoid Arthritis were followed. Analysis was done and results were calculated statistically using paired 't' test. Results obtained are encouraging and indicate the efficacy of *Panchamuladi Kaal Basti* over *Amavata* (Rheumatoid arthritis), exploring many aspects of this clinical entity.

Key words: *Amavata*, *Panchamuladi Kaal Basti*, *Rheumatoid Arthritis*.

INTRODUCTION

In Ayurveda, it is explained that *Samprapti* (pathogenesis) of almost all the diseases begins with the *Agnimandya* which leads to formation of *Aama*.^[1] This *Aama* is the utmost important causative factor for various diseases. On other hand, *Vata Dosha* is most powerful among three *Doshas* and it controls the other two *Doshas* as well as it is very difficult for treatment. Therefore, when these two factors (*Ama* and *Vata*) simultaneously take part in the *Samprapti*

(pathogenesis), then the resultant disease becomes very difficult to treat. *Amavata* is one of the most challenging diseases caused by *Aama* combining with vitiated *Vata Dosha*. The disease *Amavata* belongs to *Abhyantara* as well as *Madhyama roga marga*. The *Samprapti* (pathogenesis) starts in the *Annavaha Srotasa* and then extends through *Madhyama Roga Marga* with special inclination for *Kapha Sthanas*, especially *Sandhis* (joints).^[2] In such a condition, patient weeps in agony of pain and reduced functional capacity with severe stiffness and crippling deformity of joints, which make them bed ridden. Having several features similar to Rheumatoid arthritis, *Amavata* is generally compared with this disease. Rheumatoid arthritis is an autoimmune polyarthritis of unknown etiology with symmetrical joint involvement and effects many other systems too. There is no definite cure for the disease.

In Ayurveda, many approaches are in practice to treat *Amavata* but still remain a challenging problem. Many research works have been done on this disease, but still there is a need of an effective, safe, and less

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complicated treatment. In present study, *Basti Chikitsa* was selected for clinical trials as *Basti* is the major treatment in Ayurveda which directly acts over the *Vata Dosha* and many a times is called as *Ardha Chikitsa* or *Sarva Chikitsa*.

AIMS AND OBJECTIVES

Aim

To evaluate the efficacy of *Panchamuladi Kaal Basti* in *Amavata* w.r.t. Rheumatoid Arthritis

Objective

To evaluate the efficacy of *Panchamuladi Kaal Basti* along with on Hematological and Bio chemical parameters especially ESR and R.A. Factor (quantitative) test.

Ethical Clearance

This clinical study was ethically cleared by institutional ethical committee. The drugs used in the study were authenticated by *Dravyaguna* and *Rasashashtra* Dept. of D. Y. Patil School of Ayurveda, Nerul, Navi-Mumbai.

MATERIALS AND METHODS

Materials

Panchamuladi Kaal Basti^[4]

Sanskrit Name	Botanical name	Preparation & Dose
<i>Panchamuladi Kwatha Dravya</i>		
<i>Bilwa</i>	<i>Aegle marmelose</i>	Total amount of <i>Dhamuladi Bharad</i> is about 50 gm was taken in pot (Every drug have been taken in equal quantity) and 16 times water i.e 800ml is added in it, these pot is heated on slow flame of gas (<i>Mandyani</i>).
<i>Agnimantha</i>	<i>Premna mucronata</i>	
<i>Syonaka</i>	<i>Oroxylum indicum</i>	
<i>Kashmarya</i>	<i>Gmelina arborea</i>	
<i>Patala</i>	<i>Stereospermum suaveolans</i>	
<i>Shalaparni</i>	<i>Dasmodium gangeticum</i>	
<i>Prushniparni</i>	<i>Uraria picta</i>	
<i>Bruhati</i>	<i>Solanum indicum</i>	

<i>Kantakari</i>	<i>Solanum xanthocarpum</i>	Heating has been continus till 1/4 th liquid is remain in the pot, now these <i>Kwath</i> is ready for <i>Niruha Basti</i> . <i>Panchamuladi Kwath</i> :- 200ml.
<i>Gokshura</i>	<i>Tribulus terrestris</i>	
<i>Haritaki</i>	<i>Terminalia chebula</i>	
<i>Vibhitaki</i>	<i>Terminalia bellerica</i>	
<i>Amalaki</i>	<i>Embelica officinalis</i>	
<i>Bilwa</i>	<i>Aegle marmelose</i>	
<i>Madanaphala</i>	<i>Randia spinosa</i>	
<i>Kalka Dravya</i>		
<i>Indrayava</i>	<i>Holarrhena antidysentrica</i>	Total amount <i>Kalka</i> is about 40 gm was taken. (Every drug have been taken in equal quantity)
<i>Patha</i>	<i>Cissampelos pariera</i>	
<i>Madanaphala</i>	<i>Randia spinosa</i>	
<i>Musta</i>	<i>Cyperus rotundus</i>	
<i>Other Dravya</i>		
<i>Madhu</i>	Honey	60 ml
<i>Saindhav</i>	Sodii chloridum	05 gm
<i>Yava Kshara</i>	Potasii carbonas	05gm
<i>Eranda taila</i>	<i>Ricinus Commimunis</i>	120ml
<i>Gomutra Arka</i>	-	50ml

Methods

Research Place: Dept. of Kayachikitsa, OPD /IPD D.Y.Patil School of Ayurveda , Nerul, Navi-Mumbai.

Sample Size: 30

Type of Study: Single Arm Open Clinical Study

Basti: *Niruhavata*

Dose of *Basti Dravya*

- Asthapana Basti*** : Each *Basti* was administered in a dose of 480 ml.

- **Anuvasana Basti** : 80 ml of *Panchamuladi Taila* was administered in each *Basti*.
- **Duration** : 8 days
- **Parihara Kala** : 16 day

Inclusion criteria

1. Patients having classical features of *Amavata* like *Angamarda*, *Aruchi*, *Trishna*, *Hrillasa*, *Gaurava*, *Jwara*, *Shula*, *Shotha* etc. were selected for the present clinical research work. Detailed research proforma was prepared incorporating all the clinical features seen in the disease *Amavata* (Rheumatoid Arthritis).
2. The patients who had fulfilled the revised criteria for Rheumatoid arthritis fixed by the American college of Rheumatology in 1987. Rheumatoid factor positive and negative both cases were included.
3. Age 20-60 yrs

Exclusion criteria

1. Chronicity of more than 10 years
2. Having severe crippling deformity
3. Having cardiac disease, pulmonary tuberculosis and pregnant women
4. Age less than 18 years and more than 60 years

Laboratory investigations

- Rheumatoid Factor (Quantitative) test.^[5]
- Erythrocyte Sedimentation Rate by Westergreen method
- Serum uric acid (for exclusion)
- X-ray of the affected joint
- Routine urine, blood examination

Criteria for assessment

The results of therapy were assessed on the basis of clinical features of the disease *Amavata*, which are mentioned in Ayurvedic classic as well as with the help of criteria fixed by American Rheumatism Association in 1987. The scoring pattern adopted for assessment of clinical features is as follows:

Cardinal symptoms

Sandhi Ruja (joint pain)

1. No pain - 0
2. Mild pain of bearable nature comes occasionally - 1
3. Moderate pain but no difficulty in joint movements and requires some upashaya measures for relief - 2
4. Slight difficulty in joint movement due to pain and requires some medication and remains throughout the day - 3
5. More difficulty in the joint movements and pain is severe, disturbing sleep and requires strong analgesic - 4

Sandhi Shotha (joint swelling)

1. No swelling - 0
2. Mild swelling - 1
3. Moderate swelling and present in more than 2 affected joints - 2
4. Excessive swelling over the all affected joints - 3

Stabdhata (stiffness)

1. No stiffness or stiffness lasting for 10 to 20 minutes - 0
2. Stiffness lasting for 20 minutes to 2 hours - 1
3. Stiffness lasting for 2 to 5 hours - 2
4. Stiffness lasting for 5 to 8 hours - 3
5. Stiffness lasting for more than 8 hours - 4

Ushnata (heat over the affected joints)

1. Raised temperature when compared with normal body surface - 02
2. Fall in local warmth - 01
3. Normal temperature - 00
4. No change after the treatment - 02

Sparshasahyata (tenderness about the joints)

1. No tenderness - 0

2. Subjective experience of tenderness - 1
3. Wincing of face on pressure - 2
4. Wincing of face with withdrawal of affected part on pressure - 3
5. Resist touching - 4

General symptoms

1. Symptoms observed before treatment - 2
2. Some relief after treatment - 1
3. Complete relief after treatment - 0
4. No improvement after treatment - 2

Overall assessment of the therapy

To assess the overall effect of the therapy, the criteria laid down by ARA were adopted. Results are classified into four groups as listed below:

1. Complete remission
2. Major improvement
3. Minor improvement
4. Unimproved

OBSERVATIONS AND RESULTS

Mean, percentage, SD, SE, 't,' and P value were calculated. Paired 't' test was used for calculating 't' value. following results were found

1. *Sandhi Ruja* - t value -15.42, percentage improvement - 53.91%
2. *Sandhi Shotha* - t value - 12.04, percentage improvement - 57.63%
3. *Stabdhatta* - t value - 15.42, percentage improvement - 54.24%
4. *Ushnata* - t value - 4.709, percentage improvement - 100%
5. *Sparshasahyava* - t value -15.425, percentage improvement - 54.24%

Table 1: Showing effect of therapy on subjective parameters.

S N	Symptoms	BT	AT	t	p	Percentage improvement
1.	<i>Sandhiruja</i> (Pain)	2.3	1.06	15.42	P<0.0001	53.91%
2.	<i>Sandhi Shotha</i> (Joint swelling)	2.03	0.86	12.04	P<0.0001	57.63%
3.	<i>Stabdhatta</i> (Stiffness)	2.33	1.066	15.42	P<0.0001	54.24%
4.	<i>Ushnata</i> (local temperature)	0.433	0	4.709	P<0.0001	100%
5.	<i>Sparshasahyava</i> (tenderness)	2.33	1.066	15.425	P<0.0001	54.24%

P<0.0001 - Significant

DISCUSSION

Maximum number of patients (40%) belonged to the age group of 31-40 years, which shows its predominance in the middle age group. In this study, numbers of the female patients were (60%) as compared to male (40%). Textual references also reflect the predominance of rheumatoid arthritis in females. Patients with chronicity less than 1 year were 26.66%, between 1 to 2 years were 43.33% and more than 2 years were 30%. Highly significant results (P<0.001) were obtained in all the cardinal symptoms *Sandhi Ruja* (53.91%), *Shotha* (57.63%), *Stabdhatta* (54.24%), *Ushnata* (100%), *Sparshasahyava* (54.24%).

The improvement in the symptoms of *Aamvata* can be attributed to two major factors i.e. reduction of pain and stiffness in all joints that may be due to analgesic and anti-inflammatory effect of drugs. Pain is inherent quality of *Vata*. Most of the drugs were *Vata Kapha Shamaka* having hot potency and oleation

property there by pacifies aggravated *Vata*. Further, these improve the function of *Vyana Vayu* specifically which is responsible for the movements. Also these drugs are *Katu-Tikta Rasatmaka*, *Ushnavirya* helps to digest this *Aama* resulting in relief of symptoms like stiffness and swelling of joints.^[6]

CONCLUSION

Lastly, it can be concluded that *Amavata* looks similar to Rheumatoid Arthritis in its clinical appearance. The present treatment modality viz. *Panchamuladi Kaal Basti* is found to be effective clinically as well as statistically in the treatment of *Amavata*. Also, it gives significant results on rheumatoid factor and highly significant result on ESR which is used for diagnosis of rheumatoid arthritis. By combating *Vata Dosha* and *Ama* (the chief pathological factors), it lead to *Samprapti Vighatana* of *Amavata* and hence, highly significant results were achieved in all the cardinal symptoms.^[7] Due to limitation of number of cases and duration of the trial, there is a need to conduct further study in this regard on larger sample and for a longer duration to improve this preliminary study.

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