Clinical Study to Evaluate Role of Amavatavidhwansa Rasa in Amavata with Special Reference to Rheumatoid Arthritis.

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ABSTRACT

Amavata (Rheumatoid Arthritis) is one of those diseases which hamper quality of life of patient. It occurs in early age. Ama and Vata plays most predominant role in occurrence of this disease. As per modern science, inflammation of the synovial membrane of joints (large or small) takes place which results in swollen joints, tenderness and warmness and stiffness. Swelling, Tenderness and Stiffness limits the movements of joint involvement. Patient becomes helpless due to painful movements, its bad prognosis and longer duration. Hence it is need of time to find out effective solution in the management of Amavata (Rheumatoid Arthritis). In the present study, clinical trials were attempted in total 20 patients using randomization and control. Study group was treated with Amavata Vidhwansana Rasa while Control group was treated with Simnhad Guggulu. Each patient was observed for 30 days. Amavatavidhwansana Rasa overall gave about 68% average relief in study group and Simhanada Guggulu overall gave about 66% average relief in control group. Finally, after statistical analysis it was concluded that both the drugs were almost equally effective to reduce symptoms (Mann-Whitney’s U Test: P>0.05) and to reduce WBC, ASO, ESR (Unpaired t Test: P>0.05). No adverse effects were observed.

Keywords: Amavata, Amavatavidhwansana Rasa, Simhnada Guggulu, Rheumatoid Arthritis.

1. INTRODUCTION

Roots of most ancient medical stream (Ayurveda) are found in the Indian subcontinent. Modern medicine the globalized system of medicine called Ayurveda as Alternative or Complimentary medical stream which is not true fact as Ayurveda is not only medical science, it is a complete life science. Ayurveda is a Upaveda or auxiliary disciplined knowledge branch in Vedic tradition. Ayurveda is one of the subbranches (Upaveda) of Atharvaveda. Atharvaveda contains 114 mantra (hymns) which are indicated as magical treatment of various diseases. Amavata is the disease which makes the patient cripple causing loss of movements and physical as well as mental power loss. It is systemic as well as locomotor disorder. The name Amavata is because of its two major samprapti ghataka (pathogenic constituents) viz. Ama and Vata. Madhavakar mentioned that Amavata is a disease where Ama and Vata both play a crucial role in the samprapti. The consumption of viruddha ahara is the first ever step in the disease process of Amavata and consumption of viruddha ahara the person is having Mandagni is the main factor. Ama and Vata are main key elements but Kapha anubandha or Pitta anubandha is also involved samprapti. Vitiation of the Kapha dosha mainly Shleshak kapha along with Ama in the Amavata can be correlated with Rheumatoid Arthritis in which joint pain and swelling with tenderness is the clinical presentation and Vitiation of Pitta dosha along with Ama in the Avalambah kapha sthana, can be correlated with Rheumatic fever in which repeated fever, joint involvement (swelling, pain, tenderness), cardiac involvement (RHD in late stage) is the clinical presentation. Ama is formed again and again due to Mandagni and Mandagni occurs again and again due to Ama is the main vicious mechanism responsible for

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longer duration and longer cure process of Amavata. Further the pathological bonding of Ama with vitiated Vata, moves to different Shleshma Sthanas and Dhamanis blocking the body channels (strotravarodha). This pathogenesis ends resulting in involvement of joints giving rise to stiffness and deformity. Joint pain (Sandhi shula), Swelling (Sandhi shotha), Tenderness (Sparsahatra) and Joint stiffness (Sandhi stambha) are accompanied by deranged taste (Aruchi), indigestion (Apak), lack of enthusiasm (Alasya), feeling of heaviness (Gaurava), fever (Jwara), profound fatigue (Alasya) and swelling of joints (Shoonata). The further progresses disease (Gambhira avastha) gives rise to symptoms like migration of pain from joint to joint (sanchari vedana), stinging (Toda), burning sensation (Daha) which may be accompanied by vomiting (Chardi), giddiness (Bhrama), episodic fainting (Murchha) etc.

Amavata is the product resulted due to Jatharagni mandya (impairment of digestive power) and Dhatvagni mandya (impairment of metabolic digestive power). When Mandagni patient consumes viruddha ahara (consumption of opposite property dietary items together) and viruddha cheshta (improper work/movements at improper time) and such patients performs exercise/heavy work (Vyayan) after having oily and fat rich diet (Snigdha bhukta) then he gets suffered from Amavata. The line of treatment of Amavata comprises Langhan, Swedana, Tikta-Katu rasamk drugs, Virechan, Snehapan, Basti, Ruksa sweda, Valuka pottali sweda and Upanaha but, all strictly avoiding Sneha (Oil, Ghee etc.). Rheumatoid Arthritis is autoimmune disease, which is progressive, longer duration (chronic) arthropathy. Common clinical manifestation includes morning stiffness, symmetrical bilateral joint involvement and tenderness. In this disease, inflammation of the synovial membrane leads arthritis of joints involved (small joints of the hands, feet and cervical spine, but larger joints like the shoulder and knee), swelling, tenderness and warmness and stiffness. Which in turn further limits the joint movements. As per clinical presentation, it has to be said that, Amavata is very closely resembled to the Rheumatoid arthritis.

Need of the study:

Amavata is a painful multiple joint involvement chronic systemic disease. As per ARA criteria for the diagnosis of RA, a prevalence found was 1%. Currently available line of treatment for Amavata in modern medicine includes NSAIDs, DMERDs and Steroids which are only targeted to improve quality of life and doesn’t of curative use. Ayurvedic medicines are comparatively effective and have remote side effects though take longer duration to cure. Plan was to select one of such Ayurvedic drug which is cost effective to revalidate its efficacy in the management of Amavata. This study was carried out as pilot study to finalize the subject of PG dissertation. Hence, Amavatavidhwansana Rasa was taken as study drug and Simhanada Guggulu was taken as control drug which is well-known standard of Amavata.

2. Research Methodology

2.1. Objectives

- To study efficacy of Amavatavidhwansa Rasa and Simhanada Guggulu in Amavata.
- To compare the efficacy of Amavatavidhwansa Rasa and Simhanada Guggulu in Amavata.

2.2. Research Question

Does treatment of Amavata with Amavatavidhwansa Rasa is effective than treatment with Simhanada Guggulu or not?

2.3. Methodology of Study

Current study was carried out as pilot study in order to decide the subject of dissertation. Randomized controlled trials were done in two groups namely Study Group and Control Group. Each group contained 10 patients each of Amavata. Patients were selected and allocated to respective groups randomly (Simple Randomized Sampling technique – Lottery Method). Informed written consent was taken from each and every patient after explaining them the nature of trials in the language known to them. Amavatavidhwansa Rasa was the study drug while Simhanada Guggulu was the control drug. Each patient was treated for the period of 30 days as per the group. Study was worked out in OPD and IPD of Sant Ekanath Ayurveda Rugnalaya affiliated to PMT’s Ayurveda College, Shevgaon. Ethical clearance for the study was granted by IEC of PMT’s Ayurveda College, Shevgaon. Total duration of the study was of 6 months.

2.4. Drug Review

2.4.1. Authentication of raw material
The ingredients of the study drugs (raw material) were purchased from the markets. Raw materials were authenticated in Dept. of Dravyaguna Vigyana and Dept of Rasashastra of our institute. Details about the ingredients of the drug are mentioned in Table No. 1.

2.5. Pharmaceutical Study (Preparation)

Both drugs were prepared in Dept of Rasashastra of our Institute. Amavatavidhwansa Ras\textsuperscript{23} was prepared as per Kharaliya Rasayana Kalpana.\textsuperscript{25} Simhanada Guggulu\textsuperscript{24} was prepared as per Vati Kalpana.\textsuperscript{26}

2.6. Drug Administration

Administration of the drugs is illustrated in Table No. 2.

2.7. Selection of patients

2.7.1. Inclusion Criteria

\begin{itemize}
\item Age between 20 to 45 years.
\item Gender-Both male and female.
\item Patients showing classical signs and symptoms of Amavata.
\item Patients with less than 1 year of chronicity.
\end{itemize}

2.7.2. Exclusion Criteria

\begin{itemize}
\item Patients with joint deformity and Rheumatic nodules formed.
\item Sandhigata vata, Vatarakta.
\item DM, HIV, HBsAg, Tuberculosis of bone patients.
\item Any other major systemic illness.
\item Pregnant women.
\end{itemize}

2.7.3. Drop out Criteria

\begin{itemize}
\item Patients who will develop any severe illness during the study.
\item Patients who will not attend regular follow ups or patients who will not follow prescribed drugs properly.
\item If patient who will be unable to follow prescribed medicine and do’s/don’t measures.
\end{itemize}

2.8. Assessment Criteria

Subjective and Objective parameters were the assessment criteria to be checked out before and after treatment to assess the results.

2.8.1. Subjective parameters

A. Angamarda (Bodyache)

\begin{itemize}
\item 0: No Angamarda
\item 1: Angamarda but can perform daily routine
\item 2: Angamarda restricts daily routine
\item 3: Cannot do movements due to Angamarda
\end{itemize}

B. Aruchi (Anorexia)

\begin{itemize}
\item 0: Equal willing towards all food substances
\item 1: Willing towards some specific foods
\item 2: Willing towards only one rasa
\item 3: Willing towards only most liking food
\end{itemize}

C. Jwara (Fever)

\begin{itemize}
\item 0: No Jwara Lakshana and no fever
\item 1: Jwara lakshana present but no fever
\item 2: Jwara lakshana and fever up to 100°F
\item 3: Jwara lakshana and fever above 100°F
\end{itemize}

D. Apaka (Indigestion)

\begin{itemize}
\item 0: No indigestion and take his food at regular times
\item 1: Mild indigestion but can take his food at regular times
\item 2: Moderate indigestion and many eat once a day
\item 3: Severe indigestion and can eat only once a day
\end{itemize}

E. Shotha (Swelling)

\begin{itemize}
\item 0: No swelling
\item 1: Mild swelling covering bony prominence of the joint
\item 2: Moderate swelling covering joint capsule
\item 3: Severe swelling causing deformity of joint
\end{itemize}

F. Shoola (Pain)

\begin{itemize}
\item 0: No pain
\item 1: Mild pain and at the beginning of physical activity only
\item 2: Moderate pain and hampers physical activity
\item 3: Severe pain and present at rest also
\end{itemize}

G. Stambha (Stiffness)

\begin{itemize}
\item 0: No stiffness
\item 1: Morning stiffness only, can do routine work rest of day
\item 2: Stiffness lasting whole a day, disturbance in daily routine
\end{itemize}
3. RESULTS AND DISCUSSION

3.1. Demographic observations

Age: 7 patients were of age between 20 to 30 years and 3 patients were of age between 31 to 40 years in Study group. 6 patients were of age between 20 to 30 years and 4 patients were of age between 31 to 40 years in Control group. Out of 20 patients there were total 13 patients of age between 20 to 30 years. Early age group patients were found most as Amavata (Rheumatoid Arthritis) is the disease of early age also Kapha is pradhan dosha in early age.

Gender: 8 patients were male and 2 patients were female in Study group. 7 patients were male and 3 patients were female in Control group. There were total 15 male patients out of 20 patients. Males were found more prone to Amavata than females. It was by chance only as Amavata is common in both genders.

Agni: 9 patients were having Mand agni and 1 patient was having other agni in Study group. 7 patients were having Manda agni and 3 patients were having other agni in Control group. There were total 16 Manda agni patients out of 20 patients. It was observed so because Manda agni and Amavata both are end results of Ama.

Vihar: 9 patients were having Shita vihara and 1 patient was having Ushna vihara in Study group. 9 patients were having Shita vihara and 1 patient was having Ushna vihara in Control group. There were total 18 patients with Shita vihara out of 20 patients. Shita guna is one of the commonest hetus of Amavata.

3.3. Effect of therapy

Study was carried out in 20 patients. To find relief in patient and in turn Effect of therapy before and after symptom scores were assessed. Overall effect was calculated in the form of percentage in all 20 patients of both groups. In study group 1 patient achieved Excellent improvement (i.e. between 76% to 100%) while 6 patients achieved Good improvement (i.e. between 51% to 75%). In control group 1 patient achieved Excellent improvement (i.e. between 76% to 100%) while 6 patients achieved Good improvement (i.e. between 51% to 75%). Patient wise % relief is shown in Table No. 3 and Figure No. 5. Likewise, Effect of therapy was calculated in the form of percentage in all 7 symptoms in both groups. In study group 2 symptoms achieved Excellent improvement (i.e. between 76% to 100%), 4 patients achieved Good improvement (i.e. between 51% to 75%) while 1 symptom achieved Moderate improvement (i.e. 26% to 50%). In control group 2 symptoms achieved Excellent improvement (i.e. between 76% to 100%), 4 patients achieved Good improvement (i.e. between 51% to 75%) while 1 symptom achieved Moderate improvement (i.e. 26% to 50%). Symptom wise % relief is shown in Table No. 4 and Figure No. 6.

In study group, relief in symptoms was as follows - Aruchi 95.50%, Angamarda 88.50%, Jwara 70.6%, Apaka 60%, Shotha 52.20%, Shula 62.10% and Stambha 45% (Table No. 4). In control group, relief in symptoms was as follows - Aruchi 90.90%, Angamarda 84.60%, Jwara 70.6%, Apaka 63.20%, Shotha 52%, Shula 59.30% and Stambha 42.10% (Table No. 4). As per observed % relief in patients and in symptoms it was observed that, the drug used in study group and the drug used in control group both have shown almost equal effect to reduce symptoms of Amavata. It means, Amavatavidhwansana Rasa and Simhanada Guggulu both are almost equally effective to reduce symptoms of Amavata.

3.3. Statistical Analysis

Mann-Whitney’s U test was applied to Subjective parameters to check significance. In case all subjective parameters the test has shown insignificant difference as value of P was greater than 0.05. Unpaired t test was applied to Objective parameters to check significance. In case all objective parameters ASO, ESR and WBC the test has shown insignificant difference as value of P was greater than 0.05. According statistical analysis it was concluded that,

♦ There is no significant difference between effica-
Effect of Amavatavidhawansa Rasa and Simhanada Guggulu to reduce symptoms Aruchi, Angamar- da, Jwara, Apaka, Shotha, Shula and Stamthha in Amavata.

There is no significant difference between efficacy of Amavatavidhawansa Rasa and Simhanada Guggulu to reduce test values of parameters ASO, ESR and WBC in Amavata.

3.4. Probable mode of action

Considering samprapti of Amavata samprapti ghataka involved can be illustrated as follows. Doshas: Sama vata along with Kapahanbandha or Pittanubandha, Dushya: Rasa, Sira-kandara, Mansa, Asthi, Avastha: Sama, Strotorodha pradhan, Strotas: Annava, Rasavaha, mamsavaha, Asthivaha, Ud bhavasthantha: Amashaya & Pakvashaya both, Adhisthana: Sarva sandhi, Marga: Madhyama, Sdhyasadhya: Kashtasadhya / Yapa / Darun. In short Amavata is samatapradhan vyadhi having involvement Vatapradhan dwi (two) or tri (three) doshas.

Hence, drugs used in management of Amavata should contain following properties as Dipana, Pachana, Katutikta ras dravya, Swedana, Vata-kapha shanama, Shothagnha, Anulomana, Vedanasthapan, Aamapachaka. Such drugs should bear Laghu, Ruksha, Ushna properties also. Both the drugs Amavatavidhawansa Rasa and Simhanada Guggulu fulfill the criteria of above properties and hence having effective in the management. Details regarding mode of action of both drugs are shown in Table No. 5.

4. CONCLUSION

- Prevalence of Amavata is increasing day by day.
- Vata and Kapha are the major samprapti ghataka in Amavata along with Ama.
- Manda agni and Shita vihara are found most dominating predisposing factors for Amavata.
- Male patients and patients having Krura koshtha were found more incident in Amavata.
- Amavatavidhawansa Rasa and Simhanad Guggulu were found almost equally effective to reduce subjective and objective parameters in Amavata.
- None of the patient have shown any adverse effect during the course.

5. REFERENCES

15. Ibidem 14, Uttarardha; Chikitsasthana; Jwara Chikitsa Adhyaya: Chapter 3, Verse 139-142. p. 91.


6. TABLES AND FIGURES

<table>
<thead>
<tr>
<th>Sr. No.</th>
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<th>Simhanada Guggulu&lt;sup&gt;26&lt;/sup&gt;</th>
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<td>---</td>
</tr>
<tr>
<td>6</td>
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Table No 1 Ingredients of study drug and control drug
Duration | 30 days | 30 days
---|---|---
Follow up | Day 1, Day 15, Day 30 | Day 1, Day 15, Day 30

**Table No 2** Administration of Drugs

<table>
<thead>
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<th>Pt. No.</th>
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**Table No 3** Overall Effect in Patients

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**Table No 4** Overall Effect in Symptoms

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**Simhanada Guggulu**

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**Table No 5 Mode of Action of drugs**

**Figure No 1** Age wise distribution

**Figure No 2** Gender wise distribution

**Figure No 3** Agni wise distribution

**Figure No 4** Vihara wise distribution
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