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**Research Article** 

# EFFECT OF CLASSICAL AYURVEDIC TREATMENT IN THE FUNCTIONAL IMPROVEMENT OF PATIENTS WITH RHEUMATOID ARTHRITIS

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**KEYWORDS:** Rheumatoid Arthritis, *Ama vata, Vatarakta, Patrapottali sweda, Rasnasapthaka kwatha, Kottamchukkadi taila.* 

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#### ABSTRACT

Arthritis and various musculoskeletal disorders are the leading causes of disability in persons between 18 to 65 years of age and are common causes of disability related to employment. Among them Rheumatoid arthritis is a common clinical condition characterized by pain, stiffness and inflammation of joints with varying degree of disability. In this study 50 patients (age group between 20-60 yrs) diagnosed as RA after assessing both objective and subjective parameters have undergone the prescribed classical Ayurvedic treatments, both IP and OP level to evaluate its effect in the functional improvement. The study period was totally 57 days which includes 21 days each at inpatient and outpatient basis and 15 days of follow up. Initial course was Ama pachana treatments for 7 days. It includes Pachana medicines internally and Ruksha pottali sweda externally. Next 14 days, Samana medicines internally and Pathra pottali sweda externally were given. Same internal medicines and oil application were continued for next 21 days as outpatient. The response of treatment was assessed periodically with respective parameters and were showed significant effect. The improvement in functional assessment evaluated by using the Das 28 score, disability index, quality of life index -SF36 and global assessment of disease activity scale are all found significant changes. The lab parameters used to evaluate the liver and kidney function did not show any adverse changes that shows the prescribed treatment is safe.

#### INTRODUCTION

Rheumatoid arthritis is a systemic connective tissue disorder not only affects the synovial joints but may affect almost all the tissues or organ systems in the body. Among the musculoskeletal disorders it is a very common and distressing clinical condition owing to its chronic nature, crippling deformities and pain. The changing life style, climatic conditions and dietetic pattern are the chief contributing factors for the onset of the disease. It is reported that about 40 per cent become work disabled within five years from onset of symptoms with significant decline in functional capacity and the number of affected patients is increasing day by day. The prevalence of RA is  $\sim 0.8\%$  of the population (range 0.3-2.1%); women are affected approximately three times more often than men<sup>1</sup>.

Rheumatoid arthritis is an autoimmune disease with characteristic feature of inflammatory synovitis, typically in a symmetrical pattern which leads to erosive changes inside the joint. Usually certain specific joints such as the proximal interphalangeal and metacarpophalangeal joints are affected and the distal interphalangeal joints are rarely involved. Recent evidence suggests that antibodies to CCP (cyclic citrullinated peptide), which are generated within the synovium is the contributing factor for the synovitis<sup>2</sup>.

#### Ayurvedic review

The pathogenesis and clinical features of RA cannot be correlated to a specific disease entity described in Ayurveda. One can find in the descriptions of *Vatarakta* in classical Ayurvedic treatises as a spectrum of diseases that includes rheumatological, musculoskeletal, and other pathological conditions of skin and blood vessels. As such it may be noted that the pathogenesis and clinical features of the diseases, Rheumatoid arthritis, Gout, Psoriatic arthritis, Systemic lupus erythematosus, Cellulitis, Deep vein thrombosis, Thromboangitis obliterens etc. are comes under the per view of the broad diagnosis of *Vatarakta*.

According to Ayurvedic principles the irregular and injudicious dietary practices and physical activities are the causes for *Agnimandya* (indigestion) due to the disturbed *Pitta dosha* and its outcome is degraded *Rasa dhatu*. There exist the primary level *Dosha sanchaya* in *Koshta* and it characteristically affects the qualities of

Rasadhatu which is being converted into Rakta dhatu. The *Rasadhatu* that contains the "Ama", the outcome of improper digestion of food which is immunologically incompetent, is capable of vitiating *Rakta dhatu* during the course of Parinama. In this stage Vruddhi and Prakopa of Vata dosha may occur due to its own etiological factors and it interacts with Ama dosha leading to the functional disturbance of target organs. In the context of rheumatoid arthritis primarily there is a Dosha predominance of *Vatakapha* with the characteristic features of "Ama" in initial phase. The pathological processes initiated in this stage produces acute inflammatory response in the body with the clinical manifestation of soft tissue swelling or fluid effusion in the joints along with pain, general weakness, heaviness in the body, loss of appetite etc. This stage is considered as separate entity of disease Amavata and described in detail with Nidana, Samprapthi, Lakshana etc by the later text books of Ayurveda like Madhavanidana<sup>3</sup>, Bhaishajya ratnavally<sup>4</sup>, Chakradatha<sup>5</sup> etc.

In chronic disease conditions or after subsidence of "Ama" due to "Amapachana" measures the vitiated Vata interacts with Rakta and secondary level changes takes place in the target organs, Sakhas and Asthi sandhis. The functional disturbance of Vata dosha leads to the obstruction of Rakta in respective sites especially in peripheral vessels. Here the basic properties of Vata, such as Sukshmatva, Chalatva<sup>6</sup>, etc and Saratva, Dravatva<sup>7</sup> of Rakta are at work. As a result, the inflammatory processes actively centered at the affected joints makes severe damage to the structures participating in the joints. Obviously it is noted that the protective enzymes released due to the activities of lymphocytes and plasma cells –lysosomal enzymes-in the proliferated synovium leads to the digestion and erosion of hyaline cartilage which forms a covering of bony ends participated in the joints. When these changes are localized at joints and soft tissues the clinical features of *Vata* and *Rakta* predominance can be observed. All these pathological events will lead to severe degenerative changes in the joints and associated structures that can progress to various types of deformities in future.

In allopathic system of medicine NSAIDs are used for control of inflammation and related symptoms and the long term suppression is achieved by the DMARDs. But most of the NSAIDs have gastrointestinal side effects such as gastric ulcers with bleeding and perforations. Glucocorticoids have substantial effect on joint pain than NSAIDs but have many side effects including adrenal suppression, ulcers and osteoporosis. DMARDs reduce the progression of joint erosion but no analgesic activity and act slowly. Methotrexate also has the side effects like bone marrow, renal and hepatic suppression. None of the therapeutic interventions is curative, and therefore all must be viewed as palliative, aimed at relieving the signs and symptoms of the disease. Hence, these medications are not safe and fully effective in the management<sup>8</sup>.

Many studies have been conducted in various research and academic institutions to evaluate the efficacy and safety of herbal preparations as well as effect of various *Panchakarma* and related Ayurvedic procedures in the management of Rheumatoid arthritis.

Publication of research articles in JRAS and other reputed journals on RA are also available. Classical methods of management for RA with *Sodhana* therapy followed by *Kalavasti* is said to have significant effect (PKS nair et al)<sup>9</sup>. Study of *Kshara basti* and *Nirgundi ghana vati* (Krishna thanki et al.)<sup>10</sup> Vardhamana pippali rasayana (Patel.K etal.) <sup>11</sup> Alambushadi compound and its vasti in the management of Amavata (Rheumatoid Arthritis)<sup>12</sup>. Amrita Bhallathaka avaleha and Virechana karma (Priti Sharma et al)<sup>13</sup> Efficacy and safety of Ashwagandha and Siddha Makaradhwaj in Rheumatoid arthritis patients (Gajendrakumar et al.)<sup>14</sup> are few among them. All these studies have shown significant effect by the prescribed therapeutic procedure at various levels in the management of Rheumatoid arthritis.

The management programme of Rheumatoid arthritis is to be planned based on the involvement of Dosha dushya involvement in pathogenesis and the stage of the disease. In the initial stage of the disease or during the presence of "*Amatva*' that designated as *Amavata*, the treatment should be focused on Ama pachana and Srothosodhana. After the course of Ama pachana procedures the next programme should be Vata rakta Samana and regenerative in effect to reconstruct the degenerated tissues to avoid deformities at joints. In clinical practice, the Ayurvedic methods of management has been found very effective in relieving the distressing symptoms - pain, inflammation, protection of articular structures, maintenance of function, and control of systemic involvement. Hence in this study a systematic treatment programme based on the "Ashtavaidva" practices of Kerala is designed for the evaluation of the effect of functional improvement of Rheumatoid arthritis patients and the safety of the procedure.

#### **MATERIALS AND METHODS**

The present study is a prospective, open label, non randomized, single centered clinical trial conducted in the Ayurveda Research Foundation Hospital of the Vaidyaratnam group of institutions, Ollur, Thrisur, Kerala. It was carried out during the period of 2011-16 under Center Of Excellence research programme allotted by Ministry of AYUSH, Govt. of India. The trial programme was approved by the institutional ethics committee and the study was registered with Clinical Trial Registry of India. The protocol of the study and the CRF was approved by CCRAS, New Delhi. The patients attended with the clinical features of Rheumatoid arthritis in the OPD of Vaidyaratnam Ayurveda Research Foundation Hospital were subjected for the screening according to the inclusion criteria and American college of rheumatology (ACR) 2010 criteria. Exclusion criteria were patients who develop secondary complication of RA, severely damaged joints, unable to walk without support/ confined to wheelchair or bedridden, other types of arthritis with serious complications like bursitis, osteoporosis, steroid dependent patients / prolonged medications – anti depressants etc. Patient with poorly controlled Hypertension/Diabetes mellitus, Cardiac disease/ Heart failure, Pulmonary tuberculosis, Hepatic disorder, Alcoholic/ drug abuser, Pregnant women etc are also excluded.

Total No of 50 patients who fulfilled the above inclusion criteria were selected and enrolled for the study. The patients belong to both sex and age group between 20 and 60 years. All the selected patients were submitted the written informed consent to undergo the study as per the programme and undergone detailed clinical examination based on the CRF prepared that includes both Ayurvedic and modern parameters with respect to the physical characteristics of patients and disease conditions.

#### **Treatments and medicines**

The course of treatment includes inpatient and outpatient level of 21 days each. In the initial course of treatment at IPD 7 days has been allotted for *"Amapachana"* measures. *Amruthotharam kwatha* and *Vaiswanara churna* internally and *Ruksha pottali sweda* with *Syamaka churna* externally were given during this period. The next 14 days in IPD *Rasnasapthakam kwatha* and *Vyoshadi gulgulu churna* internally and *Pathrapottali Sweda* externally were tried. The patients were discharged from IPD and advised to continue the internal medicines for a period of 21 days at OPD level. During this period advised to do body massage with *Kottamchukkadi taila* and apply *Balaguluchyadi taila* over the scalp. All the cases were followed up for 15 days.

Table 1	1:	Treatment	schedule
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Internal				External		
Medicine	Dose	Time	No. of days	Procedure	Drug	
Amrithotharam Kwatha <sup>15</sup>	100ml	6am & 6pm	7	Ruksha pottali	Syamaka churna	
Vaiswanara churna <sup>16</sup>	3gms	6am & 6pm	7	sweda <sup>19, 21</sup>		
Rasnasapthakam Kwatha17	100ml	6am & 6pm	14	Pathrapottali	Kottamchukkadi taila-22	
Vyoshadi gulgulu churna <sup>18</sup>	3gms	6am & 6pm	14	sweda <sup>20, 21</sup>	<i>Balaguluchyadi taila<sup>23</sup></i> for scalp.	

The trial medicines were prepared in the pharmacy attached to the Vaidyaratnam Oushadhasala as per the procedures described in Ayurvedic formulary of India and under gone strict quality control methods as prescribed.

#### **Clinical assessment**

The assessment of result was made based on the scores provided to each signs and symptoms recorded periodically on 7<sup>th</sup>, 21st, 42nd and 57<sup>th</sup> day, and compared the changes to the baseline (0 day).Visual analogue scale was used to make assessment of pain by marking the severity by the patients themselves periodically. The improvement in functional assessment was evaluated by using the Das 28 score, Disability index, quality of life index SF36 and global assessment of disease activity scale.

Laboratory investigations were performed for all patients at baseline and after the full course of study. It includes routine haemogram, blood biochemistry for blood sugar, serum cholesterol, blood urea, uric acid, s.creatinin, SGOT, SGPT, S.Bilirubin, Alkaline phosphatase etc and immunological test for ACCP, RA factor, CRP and ASO. X-ray of affected joints and ECG of patients was also taken.

#### **Observation and Results**

The observations described here are based on the clinical study of 50 cases of Rheumatoid arthritis. Among them the majority were females (80%) and the predominant age group affected was 51-60years.

Age Female			Male		Total	
group	Count	Percent	Count	Percent	Count	Percent
21-30	3	7.5	2	20.0	5	10.0
31-40	9	22.5	0	0.0	9	18.0
41-50	9	22.5	6	60.0	15	30.0
51-60	19	47.5	2	20.0	21	42.0
Total	40	100.0	10	100.0	50	100.0
P-value = 0.028						

Table 2: Distribution of patients according to age and sex

As the all frequencies are very small Fisher's exact test was done. P-value is less than 0.05 which shows that there exists significant difference in the age wise occurrence in male and female.

The observations on socio demographic characteristic of the patients like educational status, occupation, living conditions, religion etc

Characteristics	Category	Frequency	Percent
Candan	Female	40	80.0
Gender	Male	10	20.0
Marital status	Married	47	94.0
Marital status	Unmarried	3	6.0
Educational	Illiterate	4	8.0
status	Academically qualified	46	92.0
Occupation	Desk Work	8	16.0
	Field work	19	38.0
	House wife	20	40.0
	Unemployed	3	6.0
Socioeconomic	APL	38	76.0
Status	BPL	12	24.0
Habitat	Urban	7	14.0
	Semi-urban	35	70.0
	Rural	8	16.0
	Hindu	36	72.0
Religion	Christian	4	8.0
	Muslim	10	20.0

Table 3: Socio-demographic characters of the patients

The *Dosha prakruti* of patients were analysed using a special proforma and it indicate that majority of patients were belongs to *Kaphapitta* (68%) and *Vata pitta* (22%) *Prakruti*.

Туре	Frequency	Percent
Kaphaja	1	2.0
Vata-Pittaja	11	22.0
Vata-Kaphaja	4 23 20 /	8.0
Pitta-Kaphaja	34 USHDHAR	68.0
Total	50	100.0

Sara analysis showed that 38% were rasa *Sara purusha, Raktha* and *Mamsa sara* belongs to 22% each and 14% and 4% are *Asthi sara* and *Medo sara* respectively.

Туре	Frequency	Percent		
Rasa/Twak	19	38.0		
Rakta	11	22.0		
Mamsa	11	22.0		
Meda	2	4.0		
Asthi	7	14.0		
Total	50	100.0		

Table 5: Distribution of patients based on Sara

The Samhanana condition of the patients showed that 40%, 38 % and 22% were the distribution for *Pravara*, *Madhyama* and *Avara* respectively. Among the 50 patients it was observed that 80% were *Madhyama satmya* and remaining 16% and 8% were *Avara* and *Pravara* respectively. In *Ahara shakthi*, it was observed that 66% were *Madhyama*, 32% were *Avara* and only 2 % were *Pravara*. While observing the *Vyama shakthi*, it was seen that 54 % were *Avara* and remaining were *Madhyama*.

Characters	Pravara	Madhyama	Avara
Samhanana	20 (40)	19 (38)	11 (22)
Satmya	2 (4)	40 (80)	8 (16)
Satva	3 (6)	39 (78)	8 (16)
Ahara shakti	1 (2)	33 (66)	16 (32)
Vyayama Shakti	0	23 (46)	27 (54)

Values within brackets are percentages

Among the studied patients, the climatic changes had influence in aggravating the disease condition in 58%. 16 % were affected with food and weather, 12% were affected with change in food, drink and weather. 14 % reported no specific reasons.

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Factors	Frequency	Percent
Nil	7	14.0
Weather	29	58.0
Food and weather	8	16.0
Food, drink and weather	6	12.0
Total	50	100.0

The observation on various factors mainly dietary habit showed 80% as non vegetarians and 20 % vegetarian.96% and 88% were alcoholic and smokers respectively. 45% of the patients had disturbance in sleep, 64% had allergy to some material. 72% had moderate stress and 24% had too much stress. Among the patients 22 % of them only had family history of RA. The physical structure showed 60% as in average built, 10% were emaciated and 28% were well built. 86% were moderately nourished, 8% were malnourished and 6% well nourished. 56 % were in normal BMI.

Among the patients studied 94 % were reported to have insidious onset.

Table 8:	Classification	based on	Onset of di	sease
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Onset of disease	Frequency	Percent
Acute	3	6.0
Insidious	47	94.0
Total	50	100.0

The chief complaints noted during admission were—pain and swelling in joints along with morning stiffness, tenderness, fever and general weakness.

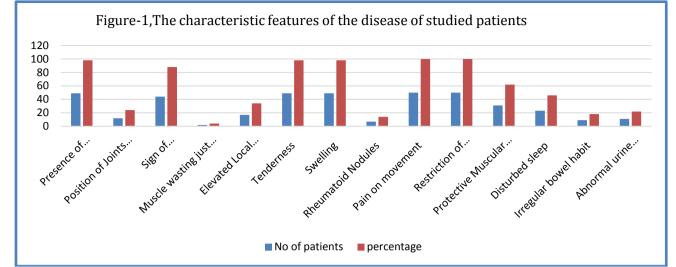
Complaints	No of patients	Percentage
Pain in Joints	50	100
Swelling in joints	49	98
Morning Stiffness	48	92
Tenderness	50	100
Fever	33	66
Malaise/fatigue/weakness	48	96

#### Table 9: Observations of Chief complaints in patients and it's percentage

The observation regarding the major signs and symptoms at the time of admission of the selected patients and its percentage of occurrence is tabulated in the table No.9

#### Table 10: The characteristic features of the disease of studied patients

Observation	No of patients	percentage
Presence of Symmetrical Poly arthritis	49	98
Position of Joints and fixed deformity	12	24
Sign of Inflammation over the joints	44	88
Muscle wasting just above the joints	2	4
Elevated Local temperature	17	34
Tenderness	49	98
Swelling	49	98
Rheumatoid Nodules	7	14
Pain on movement	50	100
Restriction of Movement	50	100
Protective Muscular spasm	31	62
Disturbed sleep	23	46
Irregular bowel habit	9	18
Abnormal urine output	11	22



Presence of *Ama* with reference to the classical features described recorded at the base line and its assessment made after the course *Amapachana* measures is tabulated in the table No-10

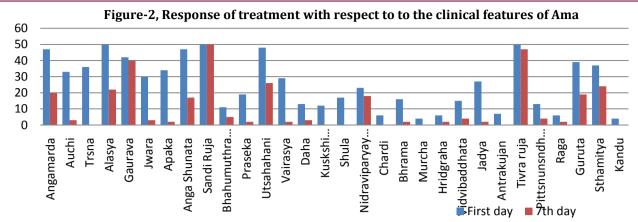
Angamarda       47       20**         Aruchi       43       3**         Trsna       36       1**         Alasya       50       22**         Gaurava       42       40ns         Jwara       30       3**         Apaka       34       2**         Anga Shunata       47       17**         Sandhistabthata       48       50ns         Sandhistabthata       48       50s         Bahumutrata       41       4**         Praseka       19       2**         Daha       13       3*         Kushi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Kushi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1ns         Bhrama       16       2**         Murcha       4       0*         Hridgraha       6       2ns         Vidvibaddhata       15       4*         Jadya       27       2** <t< th=""><th>Parameters</th><th>First day</th><th>7<sup>th</sup> day</th></t<>	Parameters	First day	7 <sup>th</sup> day
Trsna       36       1**         Alasya       50       22** $Gaurava$ 42       40 <sup>ns</sup> $Jwara$ 30       3**         Apaka       34       2**         Anga Shunata       47       17**         Sandhistabthata       48       50 <sup>ns</sup> Sandhistabthata       48       50 <sup>ns</sup> Sandi Ruja       49       50 <sup>ns</sup> Bahumutrata       41       4**         Praseka       19       2**         Utsahahani       48       26**         Vairasya       29       2**         Daha       13       3*         Kukshi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1 <sup>ns</sup> Bhrama       16       2 <sup>ns</sup> Vidvibadhata       15       4*         Jadya       27       2**         Antrakujan       7       3 <sup>ns</sup> Tivra ruja       50       47*         Pittanubamdha- daha       13       4* <tr tb=""> <tr tbody="">        Antakujan</tr></tr>	Angamarda	47	20**
Alasya       50       22**         Gaurava       42       40 <sup>ns</sup> Jwara       30       3**         Apaka       34       2**         Anga Shunata       47       17**         Sandhistabthata       48       50 <sup>ns</sup> Sandi Ruja       49       50 <sup>ns</sup> Bahumutrata       41       4**         Praseka       19       2**         Utsahahani       48       26**         Vairasya       29       2**         Daha       13       3*         Kukshi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1 <sup>ns</sup> Bhrama       16       2**         Murcha       4       0*         Hridgraha       6       2 <sup>ns</sup> Vidvibaddhata       15       4*         Jadya       27       2**         Antrakujan       7       3 <sup>ns</sup> Tivra ruja       50       47*         Pittanubamdha- daha       13       4*         Raga       6       2 <sup>ns</sup>	Aruchi	43	3**
Gaurava         42         40 <sup>ns</sup> Jwara         30         3**           Apaka         34         2**           Anga Shunata         47         17**           Sandhistabthata         48         50 <sup>ns</sup> Sandi Ruja         49         50 <sup>ns</sup> Bahumutrata         41         4**           Praseka         19         2**           Utsahahani         48         26**           Vairasya         29         2**           Daha         13         3*           Kukshi katinata         12         1**           Shula         17         6*           Nidraviparyayam         41         31*           Chardi         6         1 <sup>ns</sup> Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2 <sup>ns</sup> Vidvibadhhata         15         4*           Jadya         27         2**           Antrakujan         7         3 <sup>ns</sup> Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga <td>Trsna</td> <td>36</td> <td>1**</td>	Trsna	36	1**
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Anga Shunata       47       17**         Sandhistabthata       48       50ns         Sandi Ruja       49       50ns         Bahumutrata       41       4**         Praseka       19       2**         Utsahahani       48       26**         Vairasya       29       2**         Daha       13       3*         Kukshi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1ns         Bhrama       16       2**         Murcha       4       0*         Hridgraha       6       2ns         Vidvibaddhata       15       4*         Jadya       27       2**         Antrakujan       7       3ns         Tivra ruja       50       47*         Pittanubamdha- daha       13       4*         Raga       6       2ns         Gurutva       39       19**	Jwara	30	3**
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Sandi Ruja         49         50ns           Bahumutrata         41         4**           Praseka         19         2**           Utsahahani         48         26**           Vairasya         29         2**           Daha         13         3*           Kukshi katinata         12         1**           Shula         17         6*           Nidraviparyayam         41         31*           Chardi         6         1ns           Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Gurutva         39         19**           Sthaimitya         37         24*	Anga Shunata	47	17**
Bahumutrata       41       4**         Praseka       19       2**         Utsahahani       48       26**         Vairasya       29       2**         Daha       13       3*         Kukshi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1ns         Bhrama       16       2**         Murcha       4       0*         Hridgraha       6       2ns         Vidvibaddhata       15       4*         Jadya       27       2**         Antrakujan       7       3ns         Tivra ruja       50       47*         Pittanubamdha- daha       13       4*         Raga       6       2ns         Gurutva       39       19**         Sthaimitya       37       24*	Sandhistabthata	48	50 <sup>ns</sup>
Praseka       19       2**         Utsahahani       48       26**         Vairasya       29       2**         Daha       13       3*         Kukshi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1ns         Bhrama       16       2**         Murcha       4       0*         Hridgraha       6       2ns         Vidvibaddhata       15       4*         Jadya       27       2**         Antrakujan       7       3ns         Tivra ruja       50       47*         Pittanubamdha- daha       13       4*         Raga       6       2ns         Gurutva       39       19**         Sthaimitya       37       24*	Sandi Ruja	49 SHDHAL	50 <sup>ns</sup>
Utsahahani         48         26**           Vairasya         29         2**           Daha         13         3*           Kukshi katinata         12         1**           Shula         17         6*           Nidraviparyayam         41         31*           Chardi         6         1ns           Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Gurutva         39         19**	Bahumutrata	41	4**
Vairasya         29         2**           Daha         13         3*           Kukshi katinata         12         1**           Shula         17         6*           Nidraviparyayam         41         31*           Chardi         6         1ns           Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Gurutva         39         19**           Sthaimitya         37         24*	Praseka	19	2**
Daha         13         3*           Kukshi katinata         12         1**           Shula         17         6*           Nidraviparyayam         41         31*           Chardi         6         1ns           Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Sthaimitya         37         24*	Utsahahani	48	26**
Kukshi katinata       12       1**         Shula       17       6*         Nidraviparyayam       41       31*         Chardi       6       1ns         Bhrama       16       2**         Murcha       4       0*         Hridgraha       6       2ns         Vidvibaddhata       15       4*         Jadya       27       2**         Antrakujan       7       3ns         Tivra ruja       50       47*         Pittanubamdha- daha       13       4*         Raga       6       2ns         Sthaimitya       37       24*	Vairasya	29	2**
Shula         17         6*           Nidraviparyayam         41         31*           Chardi         6         1ns           Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Sthaimitya         37         24*	Daha	13	3*
Nidraviparyayam         41         31*           Chardi         6         1ns           Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Gurutva         39         19**           Sthaimitya         37         24*	Kukshi katinata	12	1**
Chardi61nsBhrama162**Murcha40*Hridgraha62nsVidvibaddhata154*Jadya272**Antrakujan73nsTivra ruja5047*Pittanubamdha- daha134*Raga62nsGurutva3919**Sthaimitya3724*	Shula	17	6*
Bhrama         16         2**           Murcha         4         0*           Hridgraha         6         2ns           Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3ns           Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2ns           Gurutva         39         19**           Sthaimitya         37         24*	Nidraviparyayam	41	31*
Murcha40*Hridgraha62nsVidvibaddhata154*Jadya272**Antrakujan73nsTivra ruja5047*Pittanubamdha- daha134*Raga62nsGurutva3919**Sthaimitya3724*	Chardi	6	1 <sup>ns</sup>
Hridgraha       6       2ns         Hridgraha       15       4*         Vidvibaddhata       15       2**         Jadya       27       2**         Antrakujan       7       3ns         Tivra ruja       50       47*         Pittanubamdha- daha       13       4*         Raga       6       2ns         Gurutva       39       19**         Sthaimitya       37       24*	Bhrama	16	2**
Vidvibaddhata         15         4*           Jadya         27         2**           Antrakujan         7         3 <sup>ns</sup> Tivra ruja         50         47*           Pittanubamdha- daha         13         4*           Raga         6         2 <sup>ns</sup> Gurutva         39         19**           Sthaimitya         37         24*	Murcha	4	0*
Jadya272**Antrakujan73nsTivra ruja5047*Pittanubamdha- daha134*Raga62nsGurutva3919**Sthaimitya3724*	Hridgraha	6	2 <sup>ns</sup>
Antrakujan73nsAntrakujan73nsTivra ruja5047*Pittanubamdha- daha134*Raga62nsGurutva3919**Sthaimitya3724*	Vidvibaddhata	15	4*
Tivra ruja5047*Pittanubamdha- daha134*Raga62nsGurutva3919**Sthaimitya3724*	Jadya	27	2**
Pittanubamdha- daha134*Raga62nsGurutva3919**Sthaimitya3724*	Antrakujan	7	3 <sup>ns</sup>
Raga         6         2ns           Gurutva         39         19**           Sthaimitya         37         24*	Tivra ruja	50	47*
Gurutva         39         19**           Sthaimitya         37         24*	Pittanubamdha- daha	13	4*
Sthaimitya 37 24*	Raga	6	2 <sup>ns</sup>
	Gurutva	39	19**
<i>Kandu</i> 4 1 <sup>ns</sup>	Sthaimitya	37	24*
	Kandu	4	1 <sup>ns</sup>

Table 11: Response of treatment with respect to the clinical features of Ama

\* Significant at 0.05 level; \*\* significant at 0.01 level; ns non significant (compared to base line)

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Parameters	Base Line	Visit 1 (7 <sup>th</sup> day)	Visit 3 (42 <sup>nd</sup> day)	Visit 4 (57 <sup>th</sup> day)
Pain in joints	50 (100)	50 (100) <sup>ns</sup>	27 (54)**	18 (36)**
Swelling	49 (98)	50 (100) <sup>ns</sup>	11(22)**	6 (12)**
Morning Stiffness	48 (96)	46 (92) <sup>ns</sup>	5 (10)**	2 (4)**
Tenderness	50 (100)	46 (92)*	11 (22)**	9(18)**
Fever	33 (66)	1 (2)*	0**	1 (2)**
Malaise	48 (96)	26 (52)*	5 (10)**	1 (2)**

\* Significant at 0.05 level; \*\* significant at 0.01 level; ns non significant (compared to base line)

Proportion test was used to comparing the percentage of respondents having each symptoms at different visit compared to base line. No significant difference in the pain in joints, swelling and morning stiffness was noted in the first visit. Percentage of patients having tenderness, fever and Malaise was reduced in the second visit itself compared to the base line observations. However from 22<sup>nd</sup> day on wards highly significant improvement was noted in respect of all symptoms compared to base line

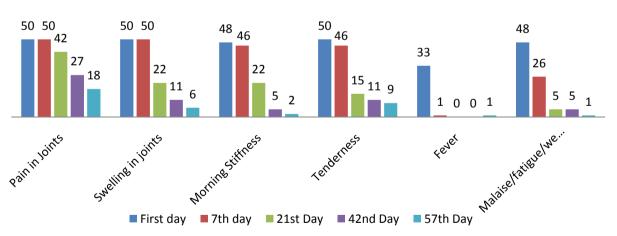


Figure-3, Response of treatment based on chief complaints using t-test

Comparison of visual analog score among different time period was compared using Friedman's test. A significant decrease in visual analog score was found from first day to  $21^{st}$  day and then to  $42^{nd}$  day.

Table 13: Comparison of Visual Analog Score		
Period	Mean ± SE	
First day	7.84 ± 0.96 <sup>a</sup>	
21 <sup>st</sup> day	3.42 ± 1.33 <sup>b</sup>	
42 <sup>nd</sup> day	1.96 ± 1.18 <sup>c</sup>	
Chi square value	93.167**	
p-value	< 0.001	

\*\* Significant at 0.01 level, Means having same letter as superscript are homogenous

Table 14: Comparison of parameters at different visit using Repeated measures ANOVA						-
Parameters	Base Line	Visit 1 (7 <sup>th</sup> day)	Visit 2 (21 <sup>st</sup> day)	Visit 3 (42 <sup>nd</sup> day)	Visit 4 (57 <sup>th</sup> day)	p-value
Das Score	6.545 ± 0.104 <sup>a</sup>	6.210 ± 0.122 <sup>b</sup>	5.524 ± 0.137°	4.897 ± 0.113 <sup>d</sup>		< 0.001
SF 36	187.66 ± 11.79 <sup>a</sup>			615.74 ± 14.35 <sup>b</sup>		< 0.001
Global assessment	21.50 ± 1.372 <sup>a</sup>	39.00 ± 1.69 <sup>b</sup>	66.20 ± 1.92°	81.70 ± 1.66 <sup>d</sup>		< 0.001
ESR	49.56 ± 3.78	52.68 ± 4.67	53.10 ± 4.29	52.30 ± 4.38		0.575
CRP	12.36 ± 1.88	11.51 ± 1.71	12.47 ± 1.84	11.23 ± 3.27		0.722
HB	11.69 ± 0.203		11.76 ± 0.182	11.68 ± 0.192		0.767
RA Factor	286.88 ± 73.19 <sup>a</sup>		268.91 ± 70.44 <sup>b</sup>	229.35 ± 55.27 <sup>b</sup>		0.040
ACCP	149.885 ± 23.87		146.40 ± 23.20	138.99 ± 20.61		0.374
Number of joints involved	23.08 ± 0.815ª		19.70 ± 0.929 <sup>b</sup>	9.48 ± 0.958°	$3.94 \pm 0.505^{d}$	< 0.001
Disability Index	1.689 ± 0.068 <sup>a</sup>	$1.300 \pm 0.066^{b}$	0.628 ± 0.059 <sup>c</sup>	$0.354 \pm 0.048^{d}$	$0.310 \pm 0.053^{d}$	< 0.001

Table 14: Comparison of parameters at different visit using Repeated measures ANOVA

Means having same letter as super script are homogeneous within a row

DAS score obtained at different measurement time were subjected to kolmogorov Smirnov test for testing normality of the observations. P-value obtained for all the four measurements was found to be greater than 0.05 which indicates that the observation was normal and hence the parametric test namely repeated Analysis of variance was done to find out whether there is any difference in DAS score at different measurement period.

Results show that there is significant difference in the DAS score measured at different days. Mean scores shows that DAS score is decreasing as the day progresses.

Comparison of SF 36 score in first day with that of 42<sup>nd</sup> day was done by using paired t-test. Results show that there exists significant difference in SF36 score in first day and 42<sup>nd</sup> day. Mean score was higher in 42<sup>nd</sup> day which indicates that SF 36 score increased form first day to 42<sup>nd</sup> day.

The Global assessment score in first day with that of  $57^{\text{th}}$  day was done and the result shows there exists significant difference in the first day and  $57^{\text{th}}$  day with mean score P < 0.001 which indicates that Global assessment increased from first day to  $57^{\text{th}}$  day.

#### **DISCUSSION AND CONCLUSION**

With reference to the ACR criteria and by using other internationally accepted scientific parameters, the evaluation of the Ayurvedic line of management for the disease has been formulated. Based on the Dosha dushva predominance and clinical features of the disease an initial course of Amapachana procedure for 7 days including specific medicines was administered. The medicines prescribed, Amruthotharam kwatha and Vaiswanara churna internally and Ruksha sweda externally is found to have significant effect in the acute stage of disease. The combination of *Guluchi*. *Hareethaki* and Shunti in specific proportion in Amruthotharam kwatha might have promoted the digestive process in Koshta and metabolic activities at Dhatu level. (antiinflammatory, immune system booster, anti rheumatic properties have already studied). In addition to that the Vaiswanara churna given internally for these days will also contributed for the same. To subside the "Ama"

*Ruksha ushna* procedure are preferred. So during this period *Rukshapottali sweda* with *Syamaka churna* was done which is also effective to reduce pain and stiffness. It is established that *Amapachana* and further protection of Agni by promoting digestion is the best choice in the treatment of RA in its acute stage. No *Snigdha prayoga* is preferred during this stage which may trigger the symptoms provoking *Doshas, Kapha* and *Vata*.

The next course of treatment in IPD was administration of Rasna sapthaka kwatha and Vyoshadi gulgulu internally and application of controlled Snigdha prayoga with Pathrapottali sweda externally. The internal medicines Rasna sapthaka Kwatha is the best choice for the relief of pain and swelling in joints as it is Sodhahara and anti inflammatory in action. The Vyoshadi gulgulu with the ingredients Thrikatu Chitraka, Musta, Thriphala, Vidanga and Guggulu are Ama pachana and Kaphamedohara also. It is very effective to improve the tissue level metabolism and the main ingredient *Guggulu* is already proved as an anti arthritis drug. The positive effect of Pathrapottali sweda in various rheumatic conditions have already established by clinical studies and practice. Swedana produces vasodilatation there by increased supply of nutrition to the site and the removal of debris or waste material generated due to the preexisted inflammatory process. It might have contributed for the positive response.

More over the application of *Pathrapottali sweda* (Snigdhasweda) causes to reduces the stiffness and to improve the mobility of the joints.. The presence of *Kapha* has been subsided in this stage and *Vata pitta* or *Rakta* predominance may be observed. The assessment of result conducted with the given parameters to evaluate the functional improvement SF-36 score, Das score, Disability index and global assessment are showed highly significant changes compared with pre treatment period which establish the effect of the therapy. After the course of inpatient level treatment the patients were advised to continue the same medicines internally and application of medicated oil, *Kottamchukkadi* externally for 21 days. The statistical evaluation made by using the above parameters also established the sustainable effect of the treatment.

Lab investigation reports were compared to the pre-treatment period to that of post treatment results did not show significant changes. The functional improvement and feeling of well being of the patients observed is an indication that there is no much relevance to the values of the lab parameters in the assessment of functional improvement. It is also to be highlighted that the liver and kidney functions did not produce any adverse changes with above line of treatment. It clearly state that the prescribed treatment did not produce any adverse effect in the body systems and it is completely safe.

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