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Research Article

A Comparative Clinical Evaluation of Pathyadi Churna and Erand Tail (Castor Oil) in the Management of Amavat (Rheumatoid Arthritis) with Special References to Gut Microbiome

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Abstract

The concept of Kaya (Agni) is unique and is responsible for bio- transformation. As it is known that energy can neither be created nor can it be destroyed. In human body, Kaya provides the necessary energy for all bodily activities. The energy provided is derived from the food we eat and the air we breathe. The biological system of the body transforms this energy to one, which is utilized by the cells. It encompasses knowledge about dispensing, dose and duration of medicine. The principles of Kayachikitsa correct Agni, Dosha, Dhatu and detoxify body thus help to cure general diseases. The rejuvenation therapy (Rasayana) of Kayachikitsa also restores physical and mental health status. The basic principles of Kayachikitsa provide ways for the management of diseases related to the disturbed pattern of lifestyle i.e. metabolic disorders. The Kayachikitsa helps to manage various metabolic disorders including obesity, hypertension, high cholesterol, fatty liver, diabetes and digestive problems. These diseases mainly occur due to the disturbed pattern of daily regimen such as irregular diet, physical exertion, stress, disturbed sleeping patterns, bad dietary habits, anger and lack of exercise, etc. The drugs such as Haritaki, Amalaki, Vibhitaki Guggulu Resin, Vidanga, *Morus Indica*, *Gymnema Sylvestre*, Kalonji and *Eugenia Jambolana*, etc. these are used as single drug choice or as a raw material for a specific formulation such as Pathyadichurna and Arand tail on which this study has been made in favour to access comparative clinical evaluation Amavat(Rheumatoid Arthritis) with Special References to Gut microbiome.

Keywords: Agni; Kayachikitsa; Amavat; Pathyadichurna; Gut microbiome

Introduction

In Ayurveda, several treatment options are available for enhancing immunity against diseases; these include certain immune-modulators known as Rasayana. Amla (*Phyllanthus emblica*), Guduchi/Giloya (*Tinospora cordifolia*), Aswagandha (*Withaniasomnifera*), Chyavanprash and Brahmarasayan are used as Rasayan and for preventing many infectious diseases. Cancer treatment in Ayurveda Ayurveda defines cancer as a chronic imbalance of Tridosha (Three bodily humours), Dhatus (tissue) and Triguna (Satwa, Raja and Tama) and can be treated without any side effect. Ayurveda can reduce the side-effects of chemotherapy and/or radiotherapy, as well as assist the body in its recovery process. Psychoimmunological rehabilitation and palliative care of advanced cancer patients can be possible through Ayurveda therapeutic procedures and medications.

These comprises the holistic approach, which is mainly concerned with the treatment of the body. In the process, the person undergoes a change in the lifestyle, which includes change in food, clothing and sometimes even residence. Ayam and vyayam, yogasadhana and gati are some of the vital components that are included in an ayurvedic treatment. Coming to kayachikitsa, it is the first branch of Astanga Ayurveda or eight-branched Ayurveda that deals with general medicine. The total treatment procedure is called Kaya Chikitsa (or internal medicine), wherein kaya means 'body' and chikitsa means 'treatment'. Kayachikitsa mainly deals with the diagnosis and treatment of a variety of general diseases, such as skin disorders, diabetes, tuberculosis, rheumatoid arthritis and many other disorders. Charaka Samhita is the most important scripture on kayachikitsa. It discussed the basic principles of treatment, various types of therapies and purification or detoxification methods. According to this natural treatment, the body of a person is product of the constant psychosomatic interactions and diseases caused are due to the imbalance caused in the tridoshas of the body. This imbalance caused in the three doshas of vata-pitta-kapha is sometimes, caused by the mind and occasionally by the body's dhatu (tissues) and mala (toxin deposits). It is then that the kayachitikitsa branch of ayurveda comes to assistance.

Kayachitikitsa is the branch of herbal and holistic medicine, which delves deep into ascertaining the root cause of the illness. The entire Ayurvedic therapeutics is based on the concept of Agni. The concept of Kaya (Agni) is unique and is responsible for bio-transformation. As it is known that energy can neither be created nor can it be destroyed. In human body, Kaya provides the necessary energy for all bodily activities. The energy provided is derived from the food we eat and the air we breathe. The biological system of the body transforms this energy to one, which is utilized by the cells. Kayachikitsa is important stream of Ayurveda that relates with the common illness and their management using natural drugs. The use of herbs, Ayurveda formulation and Shodhana therapy, etc can be utilized as approaches of Kayachikitsa for the management of different diseases including; Sosha, Jwar, Unmad, Apasmara, Atisara, Kustha and Prameha etc. Kayachikitsa provides all aspects related to the diagnosis and treatment of diseases. It encompasses knowledge about dispensing, dose and duration of medicine. The principles of Kayachikitsa correct Agni, Dosha, Dhatu and detoxify body thus help to cure general diseases. The rejuvenation therapy (Rasayana) of Kayachikitsa also restores physical and mental health status. The basic principles of Kayachikitsa provide ways for the management of diseases related to the disturbed pattern of life style i.e. metabolic disorders. The Kayachikitsa helps to manage various metabolic disorders including obesity, hypertension, high cholesterol, fatty liver, diabetes and digestive problems. These diseases mainly occur due to the disturbed pattern of daily regimen such as irregular diet, physical exertion, stress, disturbed sleeping patterns, bad dietary habits, anger and lack of exercise, etc. The drugs such as Haritaki, Amalaki, Vibhitaki Guggulu Resin, Vidanga, Morus Indica, Gymnema Sylvestre, Kalonji and Eugenia Jambolana, etc. these are used as single drug choice or as a raw material for a specific formulation such as Pathyadichurna and Arand tail on which this study has been made in favour to access comparative clinical evaluation Amavat. The study assigned as “A Comparative Clinical Evaluation of Pathyadi Churna and Erand Tail (Castor Oil) in the Management of Amavat (Rheumatoid Arthritis) with Special References to Gut Microbiome”.

Materials and Methods

A randomized, parallel-group, interventional clinical trial with 120 patients (40 per group) will be conducted. Patients will be allocated to one of three arms by computer-generated block randomization to ensure equal group sizes. The trial will be open-label due to the distinct formulations, but outcome assessors will be blinded to group allocation. Baseline characteristics (age, sex, disease duration, baseline) will be balanced by randomization. Study visits will occur at baseline and every month until 3 months, in accordance with RA management guidelines recommending regular monitoring.

A total of 120 patients, attending OPD/IPD of the SS Hospital, IMS, BHU, with the characteristic features of Amavata, will be randomly selected for the present study, between age group of 18-60 years and will be divided into 3 groups named as Group A, B and C. The details of the patients will be collected by using a standard Proforma.

120 patients will be divided into 3 groups as follows:

A total of 120 patients selected for the study groups randomly divided in to three following groups:

Group A: 40 patients clinically diagnosed and registered of Amavata fill be treated by Pathyadi Churna-5 grams (anupan Takra) twice a day for consecutive 3 months. This polyherbal powder (traditionally for deepana-pachana) is indicated for Amavata. No other anti-arthritic drug will be given.

Group B: 40 clinically diagnosed and registered patients of Amavata will be treated by-Pathyadi Churna with Erand Tail (5ml) anupan luke warm water consecutive for 3 months twice a day. Erand Tail (castor oil) is administered as a gentle purgative (Virechana) in Amavata. This tests whether the combination therapy has additive benefits.
Group C: 40 clinically diagnosed and registered patients of Amavata will he treated by Sulphasalazine-500mg BD consecutive 3 month.

Total Duration of therapy-3 months with monthly follow up every 1 month. Patients will follow a standard diet and lifestyle advice for Amavata (avoiding incompatible foods, nightly oil massage, etc.) per Ayurvedic guidelines. Use of rescue analgesics (paracetamol up to 2 g/day) is allowed for intolerable pain and use will be recorded. Use of other RA medications is prohibited during the trial.

Source of Data
A) Sample source: Minimum of 120 patients with clinical features of Amavata (Rheumatoid Arthritis) coming under inclusion criteria will be selected irrespective of gender, religion, race, socio-economic status
B) Literary source: The literary data will be collected from central library as well as Samhita and Sanskrit Department library, BHU, Varanasi.
The data also collected from relevant research articles and journals, periodicals and other published works and even from internet sources.
C) Drug source: The required drugs will be collected or purchased from authenticated vendors.
Pharmaceutical preparation- Ingredients of Pathyadi churna (Chaknadatta 25 Amavata Rogadhikar)
Pathya, Shunthi, Vavani - would be manufactured and collected from Ayurveda Pharmacy of BHU, Varanasi. (GMP Certified Pharmacy)

Clinical Study All cases will be selected from OPD/IPD Department of Kayachikisa S. S. Hospital, IMS BHU, Varanasi.

Method of Preparation of Pathyadi Churna
Required quantity of drugs is not mentioned in texts, hence according to the equality concept we will take each drug in equal quantity. Clean and crush all the ingredients to form a fine powder accordingly with the contest of indicated in chakradutta Amavata rogadhikar 25/24.

Drug Ingredients of Pathyadi Churna
Pathya- Terminalia chebula (Combretacts fumily)- (Fruit part)
Shunthi - Zingiver officinale (Zingiberscene family)- (Fruit 1 part)
Yavani - Trachyspermum azmi (Apiscese family) - (Fruit 1 part)

Method of Collection of Data
Patients fulfilling the inclusive criteria irrespective of sex, religion, socio-economic status and occupation will be enrolled for the study.

Study Design
The present study is supposed to be randomized clinical trial interventional and comparative type.

Impression
$p>0.05$-statistically not significant
$p<0.05$-statistically significant will be
$p<0.01$ or $p<0.00$)-statistically highly significant

Diagnostic Criteria
The patients will be selected on the basis of sign and symptoms mensioned in Ayurveda with the cardinal symptoms as Sandhisool, Sandhisoth, Sandhigraga, Sparsahatwa and Jwara.

Criteria for Selection

Inclusion and Exclusion Criteria

Inclusion Criteria: Adults aged 18-65 years with a clinical diagnosis of rheumatoid arthritis (Amavata) meeting the 2010 ACR/EULAR criteria. Patients must have active disease (DAS28 ≥3.2) and be willing to follow study procedures and provide informed consent. Both men and women of non-childbearing potential or using contraception are eligible.

Age between-18-60 years

Patients willing to participate for this trial.

Diagnosed cases of Amavata based on symptoms and signs described in Madhava

Nidana and ACR-FULAR 2010

Sero positive and Sero negative both cases are included

Exclusion Criteria: Patients with other inflammatory arthritis (e.g., gout, SLE), severe RA (requiring immediate IV therapy) or significant organ dysfunction (renal, hepatic, cardiac). Recent use (past 3 months) of DMARDs, biologics or systemic corticosteroids is not permitted. Pregnant or lactating women, known allergy to any study substances or participation in another trial in the past 3 months will be excluded. Patients with chronic diarrhea, bleeding disorders or bowel obstruction (contraindications to Erand Tail) are excluded.

Not willing patients

Patients with short history of less than a year

Patients having severe deformities.

Patients of Gouty Arthritis, Septic Arthritis, Osteoarthritis, Ankylosing Spondylitis,

HIV, Tuberculosis, Hypertension, D.M., and other systemic problems.

Pregnant de lactating women

Patients with major complications are like pleural effusion, ascites also excluded

Assessment Criteria

Subjective and objective parameters will be assessed based before and after treatment with appropriate statistical analysis.

Results

All the Nidanas of Amavata ultimately results in Vataprakopa and Mandagni (Ama production), initiating further pathogenesis. It is observed that symptomatology of 'Amavata'very closely resembles with the disease 'Rheumatoid Arthritis'in modern Science. 120 patients were registered for the proposed study, they were turned up for complete follow-ups and were statistically analysed and the results obtained are described below (Table 1,Fig.1).

Signs and Symptoms	Mean		Percentage (%) Relief	SD	SE	t-Value	P- Value
	BT	AT					
Angamarda	0.85	0.30	65.22	0.80	0.15	3.61	<0.05
Aruchi	1.41	0.33	76.32	0.92	0.18	6.09	<0.001
Gaurav	0.70	0.22	68.42	0.70	0.13	3.57	<0.05
Jwara	0.67	0.26	66.67	0.70	0.13	3.31	<0.05
Shunata	0.19	0.11	40.00	0.27	0.05	1.44	>0.05
Sarujam Shotha	1.48	0.33	77.50	0.99	0.19	6.03	<0.001
Agni Daurbalya	1.22	0.22	81.82	0.83	0.16	6.24	<0.001
Bahumutrata	1.11	0.85	26.67	0.82	0.16	1.87	>0.05
Nidraviparyaya	1.37	0.33	75.68	0.90	0.17	6.00	<0.001
Koshthabaddhata	1.22	0.19	84.85	0.85	0.16	6.31	<0.001

Table 1: Effect of trial drug (pathyadi churna and erand tail) in general signs and symptoms of amavata with special reference to gut microbiota.

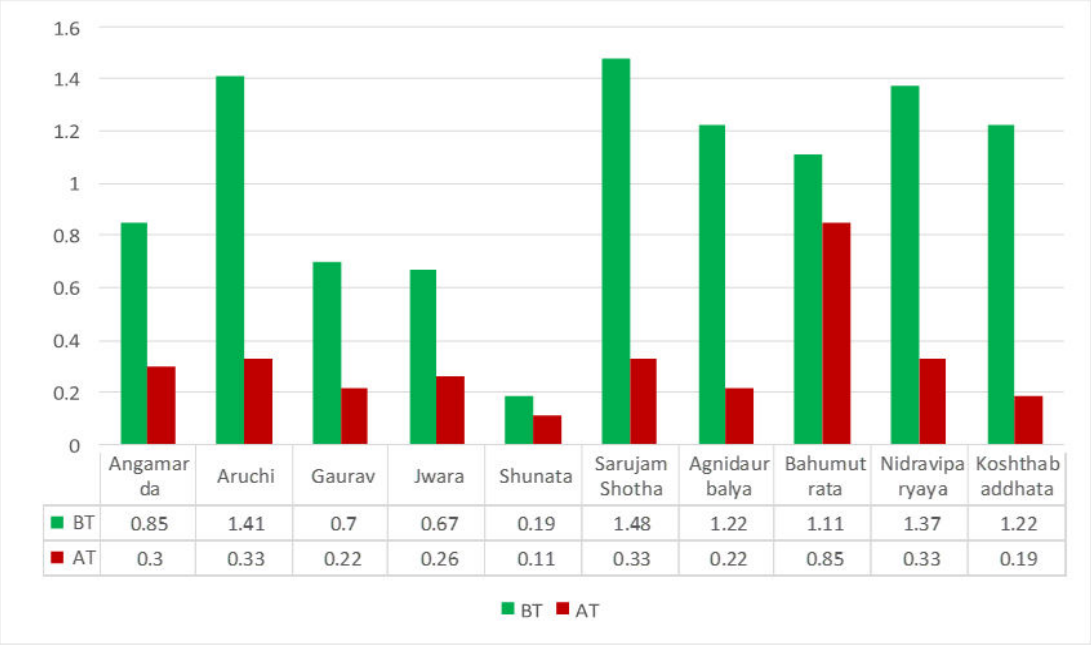

Figure 1: Effect of trial drug.

Effect of Therapy of Angamarda

Mean score of Angamarda, before treatment was 0.85 and after treatment it changed to 0.30, resulting in a 65.22% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on Aruchi:

The mean score of Aruchi, before treatment was 1.41 and after treatment it changed to 0.33 giving 76.32% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Gaurav:

The mean score of Gaurav, before treatment was 0.70 and after treatment it changed to 0.22, resulting in a 68.42% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on Jwara:

The mean score of Jwara, before treatment was 0.67 and after treatment it changed to 0.26, resulting in a 66.67% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on Shunata:

The mean score of Shunata, before treatment was 0.19 and after treatment it changed to 0.11 giving 40.00% difference in mean score which was insignificant statistically (P>0.05).

Effect of Therapy on Sarujam Shotha:

The mean score of Sarujam Shotha, before treatment was 1.48 and after treatment it changed to 0.33, resulting in a 77.50% difference in mean score which was statistically highly significant (P<0.001).

Effect of Therapy on Agni Daurbalya:

The mean score of Agni Daurbalya, before treatment was 1.22 and after treatment it changed to 0.22 giving 81.82% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Bahumutrata:

The mean score of Bahumutrata, before treatment was 1.11 and after treatment it changed to 0.85 giving 26.67% difference in mean score which was statistically insignificant (P>0.05).

Effect of Therapy on Nidraviparyaya:
The mean score of Nidraviparyaya, before treatment was 1.37 and after treatment it changed to 0.33 giving 75.68% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Koshthabaddhata:
The mean score of Koshthabaddhata, before treatment was 1.22 and after treatment it changed to 0.19 giving 84.85% difference in mean score which was statistically highly significant (P<0.001) (Table 2,Fig. 2).

Signs and Symptoms	Mean		Percentage (%) Relief	SD	SE	t-Value	P-Value
	BT	AT					
Pain	1.63	0.37	77.27	0.90	0.17	7.25	<0.001
Stiffness	1.44	0.33	76.92	0.89	0.17	6.48	<0.001
Swelling	1.59	0.30	81.40	0.91	0.18	7.38	<0.001
Mobility	0.93	0.41	56.00	0.85	0.16	3.17	<0.05
Tenderness	1.26	0.48	61.76	1.12	0.22	3.61	<0.05

Table 2: Effect of trial drug (pathyadi churna and erand tail) in cardinal signs and symptoms of amavata.

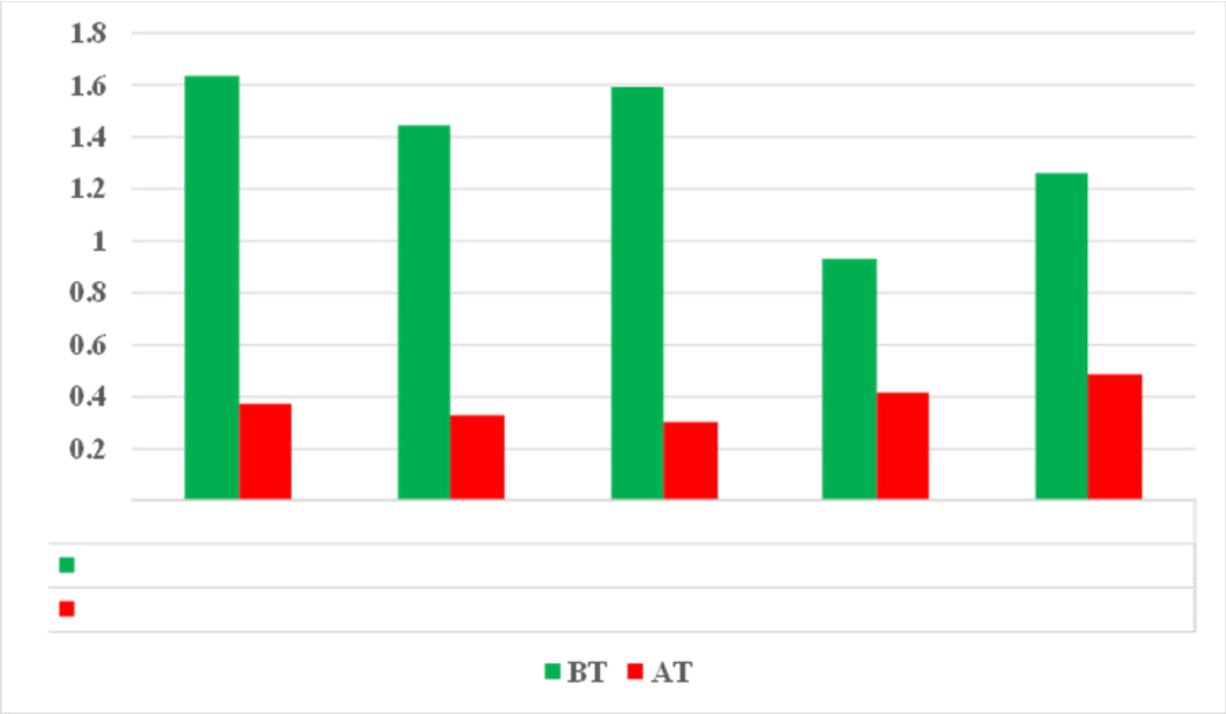

Figure 2: Effect of trial drug.

Effect of Therapy on Pain:
The mean score of Pain, before treatment was 1.63 and after treatment it changed to 0.37 giving 77.27% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Stiffness:
The mean score of Stiffness, before treatment was 1.44 and after treatment it changed to 0.33 giving 76.92% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Swelling:
The mean score of Swelling, before treatment was 1.59 and after treatment it changed to 0.30 giving 81.40% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Mobility:
The mean score of Mobility, before treatment was 0.93 and after treatment it changed to 0.41 giving 56.00% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on Tenderness:
The mean score of Tenderness, before treatment was 1.26 and after treatment it changed to 0.48 giving 61.76% difference in mean score which was significant statistically (P<0.05) (Table 3,Fig. 3).

Haematological Value	Mean		Percentage (%) Change	SD	SE	t-Value	P-Value
	BT	AT					
TLC	8925.93	7651.85	14.27	1402.08	269.83	4.72	<0.001
Neutrophils	65.26	62.89	3.58	4.19	0.81	2.90	<0.05
Lymphocyte	29.44	31.96	8.55	5.99	1.15	-2.18	<0.05
Eosinophils	2.63	2.52	4.23	1.01	0.19	0.57	>0.05
Monocytes	2.26	2.22	3.28	1.04	0.20	0.37	>0.05
Basophils	0.41	0.40	2.73	0.57	0.11	0.10	>0.05
Hb%	12.45	12.64	1.55	0.43	0.08	-2.35	<0.05
ESR	29.74	23.19	22.04	10.78	2.08	3.16	<0.05
RA factor	16.11	14.07	12.64	3.77	0.72	2.81	<0.05

Table 3: Effect of trial drug (pathyadi churna and erand tail) on haematological values.

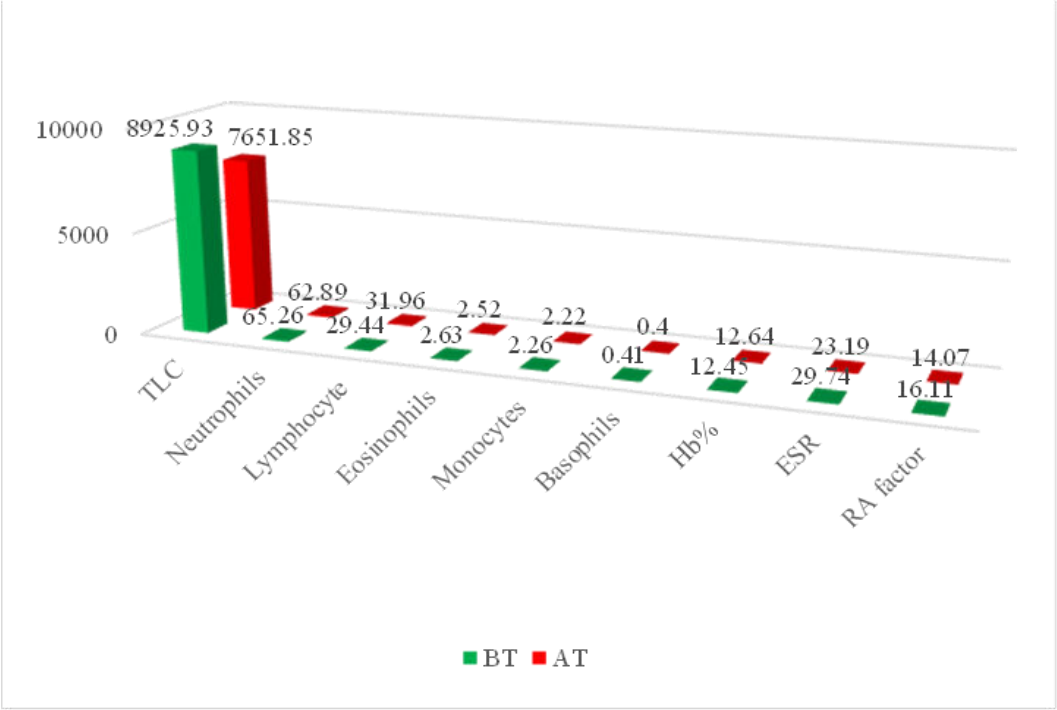

Figure 3: Effect of trial drug.

Effect of Therapy on TLC
The mean score of TLC, before treatment was 8925.93 and after treatment it changed to 7651.85 giving 14.27% difference in mean score which was highly significant statistically (P<0.001).

Effect of Therapy on Neutrophils
The mean score of Neutrophils, before treatment was 65.26 and after treatment it changed to 62.89 giving 3.58% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on Lymphocytes
The mean score of Lymphocytes, before treatment was 29.44 and after treatment it changed to 31.96 giving 8.55% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on Eosinophils
The mean score of Eosinophils, before treatment was 2.63 and after treatment it changed to 2.52 giving 4.23% difference in mean score which was statistically insignificant (P>0.05).

Effect of Therapy on Monocytes
The mean score of Monocytes, before treatment was 2.26 and after treatment it changed to 2.22 giving 3.28% difference in mean score which was statistically insignificant (P>0.05).

Effect of Therapy on Basophils
The mean score of Basophils, before treatment was 0.41 and after treatment it changed to 0.40 giving 2.72% difference in mean score which was statistically insignificant (P>0.05).

Effect of Therapy on Hb%
The mean score of Hb%, before treatment was 12.45 and after treatment it changed to 12.64 giving 1.55% difference in mean score which was statistically significant (P<0.05).

Effect of Therapy on ESR
The mean score of ESR, before treatment was 29.74 and after treatment it changed to 23.19 giving 22.04% difference in mean score which was significant statistically (P<0.05).

Effect of Therapy on RA Factor
The mean score of RA factor, before treatment was 16.11 and after treatment it changed to 14.07 giving 12.64% difference in mean score which was significant statistically (P<0.05).

All the patients selected in the present study were between the age group of 21 to 70 years, with most of the patients were in the age group of 41-60 years. Maximum patients of this study were females (66.67%), married (86.67%), housewives (60.00%) and Hindu (96.67%). Most of the patients were low economical class (56.67%) and educated (66.66%). Maximum patients of this study had Vata-Kapha prakriti (66.67%),Majority of the patients each were having Madhyama Sanhanana (80.00%), Madhyama Satva (80.00%) and also Madhyama Satmya (83.33%). Most of the patients were vegetarians (76.67%) and having addiction of tea/coffee (73.33%). Most of the patients had family history of joint pain (70.00%), maximum patients (70.00%) had persistent pain and 56.67% patients were seropositive for Rheumatoid factor.Patients developed complications of 'Amavata' in their fourth decade of age. Chronicity of the disease in most of the patients (73.33%) were between 6 to 10 years. Most of the patients of this study had reduced sleep at night (73.33%). Most of the patients (i.e 86.67%) had symmetrical joint involvement. In general signs and symptoms of Amavata, all the 27 patients (i.e 100.00%) were suffering from Sarujamshotha, Angamarda was found in 18 patients (i.e 66.67%), Aruchi, Agnidaurbalya and Nidraviparyaya were found in 24 patients (i.e 88.89%), Gaurav was found in 14 patients (i.e 51.85%), Jwara was found in 13 patients (i.e 48.15%), Shunata was found in 04 patients (i.e14.81%), Bahumutrata in 16 patients (i.e 59.25%) and Kosthabaddhata in 22 patients (i.e 81.48%). In Cardinal signs and symptoms of Amavata, all the 27 patients (i.e 100%) suffered from pain, stiffness and swelling, 21 patients (i.e 77.78%) suffered from restricted mobility and 24 patients (i.e 88.89%) suffered from tenderness. This therapy provided statistically highly significant relief in general signs and symptoms such as Aruchi, Sarujam Shotha, Agni Daurbalya, Nidraviparyaya and Koshthabaddhata, while providing statistically significant relief in Angamarda, Gaurava and Jwara. The therapy provided statistically highly significant relief in cardinal signs and symptoms such as Pain, Stiffness and Swelling while providing statistically significant relief in Mobility and Tenderness. The therapy provided statistically highly significant change in TLC while providing statistically significant change in Neutrophils, Lymphocyte, Hb%, ESR and RA factor.

Conclusion

The comparative analysis of drug efficacy across all the three groups revealed that Group B having use of both Pathyadi Churna with Erand tail exhibited significantly greater therapeutic response as compared to both the Group using Pathyadi Churna named as Group A and Group using Sulphasalazine named as Group C. The mean improvement score in Group B was substantially higher, suggesting that the drug Pathyadi Churna along with the use of Erand tail is particularly more efficient in the population for manasing the disease Amavat considering the treatment aspects with special references to Gut microbiota by this group.

Statistical testing confirmed these observations:

- The difference in efficacy between Group B and Group A was statistically significant with a p-value of 0.008, indicating high significance ($p < 0.01$)
- The comparison between Group B and Group C yielded an even lower p-value of 0.001, which is considered highly statistically significant ($p < 0.001$)
- In contrast, the difference between Group A and Group C did not reach statistical significance, with a p-value of 0.27, which is well above the conventional threshold of 0.05. This suggests no meaningful difference in drug efficacy between these two groups

These findings provide strong evidence that the Pathyadi Churna and Erand taila is clinically more efficacious for the management Amavat (Rheumatoid arthrittis) as in Group B, while the use Pathyadi Churna or Sulphasalazine alone is clinically less efficient as in Groups A and C respectively as we cancidered Gut microbioma in referance. The results underscore the importance of targeting the treatment to the appropriate subgroup to achieve optimal clinical outcomes.

Conflict of Interest

The authors have declared no conflict of interest.

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