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Classical Ashtavaidyan Ayurvedic Therapy in the functional improvement of patients of Psoriatic Arthritis - An open label, single arm exploratory clinical study

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ABSTRACT

Background: Arthritis and various musculoskeletal disorders are the leading cause of disability in persons between 18 to 65 years of age. Psoriatic arthritis simulates Ayurvedic descriptions of the clinical syndrome - *Vatarakta*. The study has been designed to evaluate the effectiveness of classical Ashtavaidyan methods of Ayurvedic intervention in the management of psoriatic arthritis and to assess the safety of the therapy. **Methodology:** Diagnosed cases of psoriatic arthritis (n=30) (20-60 yrs) have undergone the prescribed classical Ashtavaidyan Ayurvedic therapies. The total study period was 57 days which included 21 days each at inpatient and outpatient basis and 15 days of follow up. Initially modified *Takradhara* was performed along with internal medications for first 14 days; later same internal medication was continued with *Sarvanga Abhyanga* (therapeutic massage) with *Pinda Taila* and *Vajraka Ghrita* in 3:1 ratio externally and *Amalaki Thalam* for next 7 days. Same internal medicines and oil application were continued for next 21 days as outpatient. **Results:** The response to treatment was assessed periodically with respective parameters and showed highly significant improvement ($P<0.001$). There was significant reduction in PASI score and also significant changes in functional parameters related to psoriatic arthritis evaluated by using the visual analogue pain scale, DAS score, disability index scores and SF-36 (quality of life Index). The laboratory parameters used to evaluate the liver and renal functions did not show any significant changes that indicate the prescribed treatment is safe. **Conclusion:** Traditional Ashtavaidyan Ayurveda therapy is effective in reducing the skin lesions and improving functional ability in Vatarakta vis-à-vis psoriatic arthritis over a period of 42 days. Moreover, there was no adverse drug reaction recorded as well no significant change observed in liver and renal function tests.

Key words: *Ayurveda, Psoriatic Arthritis, Vatarakta, Takradhara, Functional Improvement, Vajraka Ghrita.*

INTRODUCTION

Psoriatic arthritis (PsA) is a chronic disease characterized by a form of inflammation of the skin (psoriasis) and joints (arthritis).[1] Its features are patchy, raised, red areas of skin inflammation with scaling. Psoriasis often affects posterior of the elbows and anterior aspect of knees, scalp, ear and navel, lumbo-sacral and around the genital areas or anus. Approximately 10% of patients who have psoriasis also develop an associated inflammation of their joints. Patients who have inflammatory arthritis and psoriasis are diagnosed as having psoriatic arthritis.[2]

The onset of psoriatic arthritis generally occurs in the fourth and fifth decades of life. Males and females are affected equally. The skin disease (psoriasis) and the joint disease (arthritis) often appear separately. In 60–70% of cases, psoriasis precedes joint disease. In about 15–20% of cases, the arthritis precedes the onset of psoriasis and can present a diagnostic

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challenge. Pain, swelling, or stiffness in one or more joints is commonly present in psoriatic arthritis.[3]

The cause of psoriatic arthritis is not clearly known but combination of genetic, immune and environmental factors are likely to be involved.[4] The estimates of the prevalence of psoriatic arthritis among individuals with psoriasis range from 5 to 30%.[5] the diagnosis of PsA is primarily clinical, based on the presence of psoriasis and characteristic symptoms of joint involvement.[6]

Non-steroidal anti-inflammatory drugs constitute the mainstay of pharmacological therapy for most patients. Early use of methotrexate, is indicated in patients with a poor response to NSAIDs or those with polyarticular and progressive joint involvement.[7]

In Ayurveda symptomatology of psoriatic arthritis can be correlated to the reference of *Vatarakta* in a broader sense. The characteristic feature of psoriatic arthritis, skin disease precedes the arthritis, can be observed in *Uthana* and *Gambeera* stages of *Vatarakta*, where in *Sushruta Samhitha Chikitsa Sthana*, it is explained that the disease *Vatarakta* first manifest as *Uthana* type with cutaneous manifestations and on passing of time it affects the deeper *Dhatu* (tissue) and form the *Gambheera Vatarakta*.[8] In *Uthana Vatarakta,* the disease activity and clinical features are confined to *Twak* (skin) and *Mamsa Dhatu* (muscle) causing symptoms such as *Kandu* (itching), *Daha* (burning sensation), *Ruja* (pain), *Toda*, *Akunchana*, *Bheda* (different types of pain), *Spurana* (fasiculations), *Gourava* (heaviness), *Suptata* (numbness) and *Syavata* (discolouration), *Raktatwak* (redness of skin) which denotes painful joints associated with skin lesions.[9]

The *Purva Rupa* (prodromata)of *Vatarakta* is same as the *Kushta* (skin disease) with the symptoms, *Asweda* (lack of sweating), *Atisweda* (excessive sweating), *Sparshaghnata* (numbness), *Vaivarnyam* (discoloration), *Twak Parushyam* (roughness of skin), associated with *Sandhiruk* (joint pain).[10] These symptoms involve both skin and joints which is observed in psoriatic arthritis. In *Vatarakta*, when *Vata* gets vitiated along with *Rakta*, it imparts such qualities as *Rukshta* and *Laghuta* to *Rakta* thereby bringing about the qualitative and quantitative changes in the *Rakta Dhatu* itself.[11] The vitiation of *Vata* and *Rakta* results in the deterioration of *Prakruta Karma* leading to *Vaivarnya* (discoloration) and *Krishata, Sandhi Vedana* (pain), *Toda, Santapa* (burning sensation) increased *Kleda* in the *Rakta* creates an atmosphere conducive to the occurrence of skin changes which can be justified by the treatments mentioned in *Rakta / Pittadhika Vatarakta* such as *Sheeta Pradeha / Seka, Virechana, Rakta Mokshana, Ghrita Ksheerapanam*, and all the internal and external medicines and treatments that pacify the *Rakta* and *Pitta*.[12]

In the present day living condition, incidence of psoriatic arthritis is increasing due to the improper food habits and stress and strain of various types. Since there is no satisfactory treatment in other systems for complete cure of this disease, the traditional practice of *Ashtavaidyan* line of management has been validated clinically in psoriatic arthritis to prove its safety and effectiveness in scientific lines.

Methodology

The study was an open, single arm, clinical study. The setting of the study was inpatient (IP) and outpatient (OP) department levels of Vaidyaratnam Ayurveda Foundation, Centre of Excellence for Ayurvedic Management of Chronic Joint Disorders, Ollur, Thrissur, Kerala and The study was carried out between years 2011-2016 under Centre of Excellence for Ayurvedic Management of Chronic Joint Disorders scheme allotted by Ministry of AYUSH, Govt. of India. The clinical trial was approved by the Institutional Ethics Committee and the study was registered with the Clinical Trial Registry of India (CTRI/2018/09/015820). The protocol of the study and the case report form (CRF) was prepared as per the direction and suggestions by Central Council for Research in Ayurvedic Sciences, New Delhi.

Patient selection

Thirty participants of psoriatic arthritis patients satisfying the inclusion criteria were recruited to the

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study. Those patients with multiple joints pain associated with complaints of psoriatic skin lesions and the nail changes were diagnosed as psoriatic arthritis. The age groups of patients selected were between 20-60 years. The patients who had secondary complications and long duration of the disease, steroid dependent, prolonged medications, other systemic disorders such as diabetes mellitus, essential hypertension, other arthritis like gout, osteo-arthritis, rheumatic fever, rheumatoid arthritis, ankylosing spondylitis, gonorrheal / syphilitic arthritis, arthritis with malignancy, acute pyogenic arthritis, tubercular arthritis and osteomyelitis as well as pregnant and lactating women were excluded from the study.

Informed consent was obtained from all the participants and detailed clinical examination was done based on case record form. During the course of treatment, the subjects who had developed any serious condition or any serious adverse events which requires urgent treatment or if patient himself want to withdraw from the study, were withdrawn from the trial.

Table 1: Ashtavaidyan Ayurvedic Treatment Protocol

Internal				**External**	
Medicine	**Dose**	**Time of administration**	**Duration**	**Procedure**	**Drug**
Manibhadram Leham followed by *Rasnerandadi Kashaya*	10gm	Morning 6am	21 days (IPD) and 21days (OPD)	*Takradhara* For 1-14 days	*Amalaki* and *Yashtimadhu*
	100 ml				*Pinda Taila* and *Vajraka Gritha* (3:1)for application over body
Rasnerandadi Kashaya and *Kaishora Guggulu*	1.5gm		(IPD) and 21days (OPD)	15-21 days	and *Vajraka Gritha* (3:1)for application over body *Asanavilwadi Taila* for scalp
Vajraka Ghritam	10ml	8pm	21 days (IPD) and 21days (OPD)	*Thalam* for 15-21 days (30 min at evening)	*Amalaki Kalkam*

The course of therapy included treatment both inpatient and outpatient level for a period of 21 days each. During initial course of 21 days of inpatient admission, Internal medicines were *Manibhadra* Leha[13] (10 gm) followed by *Rasnerandadi Kashaya*[14] (100 ml) at morning 6am and the same *Kashaya* with *Kaishora Guggulu*[15] tablet at evening 6 pm and *Vajraka Ghrita*[16] (10 gm) at 8 pm. Externally, from 1st-14th day, *Takradhara* processed with *Amalaki* and *Yashtimadhu* was performed. From day 15 to 21st day, *Sarvanga Abhyanga* with *Pinda Taila* [17] mixed with *Vajraka Ghrita* in the ratio of 3:1 and *Asanavilwadi Taila* [18] on scalp and *Thalam* with *Amalaki Kalka* were given, during IP treatment. The internal medicines were continued during 21 days of OP treatment and externally, *Abhyanga* was also advised.

The raw materials of trial medicines were identified and authenticated and undergone strict quality control evaluation as per the guidelines described in Ayurvedic Formulary of India in the laboratory of CARE Keralam, Thrissur. Trial medicine was prepared in the Vaidyaratnam Oushadhasala Pvt. Ltd., Thrissur, Kerala which is GMP certified Ayurveda pharmacy.

The assessment of result was made based on the scores provided to each signs and symptoms recorded periodically on 21st, 42nd and 57th day and compared the changes to the baseline. Laboratory investigations

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were performed for all the patients at baseline and after the full course of the treatment. This includes haemogram, biochemical parameters namely blood glucose, serum cholesterol, uric acid, liver function test, renal function test, C-reactive protein and ASO titer and X-ray of affected joint. The functional parameters were recorded using the validated scales - visual analogue pain rating scale, DAS score, SF-36, disability index and global assessment scale.

Statistical analysis was performed using SPSS version 20; Friedman's test and repeated measures ANOVA and details are given in the result section.

Observations and Results

Socio-demographic Profile

Table 2: Socio-Demographic Characteristics of the Patients

Characteristics	Category	Frequency	Percent
Gender	Female	9	30.0
	Male	21	70.0
Age group (yrs)	Below 20	2	6.7
	21-30	7	23.3
	31-40	4	13.3
	41-50	11	36.7
	51-60	6	20.0
Marital status	Married	23	76.7
	Unmarried	7	23.3
Educational status	Illiterate	2	6.7
	Read and write	28	93.3
Past Occupation	Desk Work	11	36.7
	Field work with physical labor	11	36.7
	Field work	6	20.0
	No Occupation	2	6.7
Habitat	Urban	5	16.7
	Semi-urban	17	56.7
	Rural	8	26.7
Religion	Hindu	25	83.3
	Christian	2	6.7
	Muslim	3	10.0

The *Deha Prakriti* of patients were analysed using a special proforma and it indicate that the majority of patients belongs to *Pitta-Kaphaja* (53.3%) and *Vatapittaja* (40%) *Prakriti*. *Sara* analysis showed that majority were *Rasa* and *Rakta Sara* (23% each), *Mamsa* and *Asthi Sara* (20% each). The physiological characters such as *Satmya, Satva, Ahara Shakti, Vyayama Shakti* of patients were also assessed which showed majority of them belongs to *Madhyama* category. The assessment of *Samhana* falls in the group of *Pravara* type.

Disease profile

The majority of patients had an insidious onset (83.3%) and remaining 16.7 % was with acute onset. 26.7% of participants were having a recent onset with less than 6 months duration and the rest were between 12- 60 months interval. In 66.7% of participants there was a previous history of illness. Aggravating factors are given in (Table 3).

Table 3: Aggravating factors

Factors	Frequency	Percentage
Food	3	10.0
Weather	17	56.7
Food and weather	8	26.7
Food, drink and weather	2	6.7

Results

Effect on joint parameters

The assessment of chief complaints at the baseline of treatments were pain in joints (100%), swelling in joints (86.7%) morning stiffness (93.3%) tenderness (96.7%) fever (23.3%), general weakness (96.7%) and skin lesion (100%). Proportion test was used to compare the base line percentage to the percentage of reduction of each symptom at consecutive visits. Significant reduction was observed in all symptoms in

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the first periodical assessment itself. The statistical evaluation of the chief complaints such as joint pain, swelling and skin lesions and other symptoms have got significant response with P< 0.01(Table 4).

Table 4: Comparison of joint complaints at different visits

Complaints	First day	21st Day	42nd Day	57th Day
Pain in Joints	30 (100)	16 (53.3)[a]	6 (20.0)[a]	3 (10.0)[a]
Swelling in joints	26 (86.7)	3 (10.0)[a]	-	-
Morning Stiffness	28 (93.3)	1 (3.3)[a]	2 (6.7)[a]	1 (3.3)[a]
Tenderness	29 (96.7)	6 (20.0)[a]	3 (10.0)[a]	2 (6.7)[a]
Fever	7 (23.3)	-	-	-
Malaise/fatigue/weakness	29 (96.7)	2 (6.7)[a]	1 (3.3)[a]	-
Skin lesion	30 (100)	23 (76.7)[a]	12 (40.0)[a]	4 (13.3)[a]
Values within brackets are percentages; [a] significant at 0.01 level; ns non significant (Compared to base line)				

FUNCTIONAL PARAMETERS

Effect on Joint pain

Table 5: Comparison of various parameters at different visits

Parameters	First day	21st day	42nd day	57th day	F	P
PASI score	22.03±2.5	4.297 ± 0.727	1.28 ± 0.304	0.51± 0.133	72.533	< 0.001
VAS Score	7.07 ± 0.23	2.90 ± 0.26	1.47 ± 0.16	-	57.474	< 0.001
Joints involved	18.00 ± 1.30	1.23± 0.49	-	-	13.88	< 0.001
DAS score	5.559± 0.179	4.212 ± 0.208	3.84 ± 0.198	-	80.354	< 0.001
Disability index	1.375± 0.071	0.375 ± 0.056	0.14 ± 0.054	0.118 ± 0.062	164.31	< 0.001

Pain score: Analysis of visual analogue pain score between different treatment intervals was made using Friedman's test. A significant decrease was noted at 21st day and 42nd day compared to the baseline data. Number of joints affected were noted at the time of admission and in intervals of 21st, 42nd and 57th day and found that there was a significant reduction in the number of the affected joints (P<0.001) (Table 5).

DAS score obtained at different measurement time were subjected to repeated measures ANOVA and results show that there is a significant reduction from the first day to 21st day. No significant difference was noted between day 21 and day 42.

Disability index assessed at various treatment intervals were subjected to repeated measures ANOVA show that there is a significant reduction. (Table 5).

Effect on psoriasis related parameters

Comparison of PASI score among different time period was done and it was found that there was a significant decrease in PASI Score (P<0.001) from first day to 42nd day and then to 57th day. (Table 5).

Biochemical parameters

The biochemical and hematological parameters namely ESR, CRP, Hb% were compared to the pre-treatment period to that of post treatment results and it was observed that there was no significant change. This indicates that therapy is safe following the prescribed medications and therapy.

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Table 6: Observation on Liver and Renal Function Tests

Parameters	Day 1	Day 21	Day 42	F-value	P-value
Blood urea	28.7 ± 1.29	28.4 ± 1.01	27.07 ± 0.9	1.011^{ns}	0.358
Uric Acid	5.19 ± 0.24	5.14 ± 0.25	5.07 ± 0.28	0.216^{ns}	0.806
Serum Creatinine	0.87 ± 0.03	0.85 ± 0.03	0.85 ± 0.02	0.694^{ns}	0.504
SGOT	33.00 ± 2.53^{a}	28.03 ± 1.79^{b}	28.30 ± 1.67^{b}	5.154*	0.014
SGPT	35.27 ± 2.62	31.4 ± 2.22	31.33 ± 2.88	1.918^{ns}	0.166
Total Protein	7.7 ± 0.12	7.74 ± 0.1	7.71 ± 0.11	0.039^{ns}	0.962
S. Albumin	4.19 ± 0.05	4.18 ± 0.05	4.25 ± 0.05	1.439^{ns}	0.245
S. Globulin	3.52 ± 0.12	3.58 ± 0.1	3.44 ± 0.11	0.501^{ns}	0.609
S. Bilurubin	0.94 ± 0.06^{a}	0.81 ± 0.04^{b}	0.8 ± 0.04^{b}	4.458*	0.016
S. alkaline Phosphates	122.43 ± 8.18	117.3 ± 8.04	125.03 ± 9.64	0.923^{ns}	0.345

*** Significant at 0.01 level; * significant at 0.05 level; ns - non significant*

Overall assessment of response of the course of treatment was noted by the physician and patient. From physician observation, it was found that 16.7% with complete (75-100%), 53.3% had good relief (50-75%) and 4% partial (25-50%) relief. On patient's assessment showed 26.7% complete relief, 70% good relief, and 3.3 % partial relief. Comparison of SF 36 score in first day with that of 57th day was done by using paired t-test. Results show that there was significant reduction in SF-36 score in patient (Table 7).

Table 7: Comparison of SF- 36 Score

Period	Mean ± SE
First day	217.457 ± 16.21
57th day	665.82 ± 17.66
t-value	18.966**
P-value	< 0.001

*** Significant at 0.01 level*

Discussion

As described earlier psoriatic arthritis can be compared with *Vatarakta* where the symptoms such as painful joints associated with swelling and skin lesions are the characteristic features. The *Ashtavaidyan* Ayurvedic line of treatment for the disease has been formulated according to the *Dosha* involvement. According to the classical reference the management of *Vatarakta* is stated as *"Virechya Snehithvath Aadau Snehayukthe Virechanaihi, Ruksharva Mridubhi Shastham Asakruth Basthikarmam Cha, Seka Abhyanga Pradehan Snehaparyo Avidahinaha, Vatarakte Prashayante"* [12] in *Vatarakta* patients initially advised oleation treatment followed by *Snehayuktha Virechana* but if patient is excessively unctuous then *Mridu Virechana* with *Rukshadravya* (*Tikshana Virechana* should not be done because it creates *Vataprakopa*), later basti should be planned frequently followed by treatments like *Seka*, *Abhyanga*, food and *Sneha* which do not cause burning sensation.

The response of treatment was assessed by the changes observed in the parameters used for the assessment at fixed intervals. The signs and symptoms used as the criteria of assessment for the response of treatment at the periodical intervals were compared with the baseline and found that all the assessment parameters have significant positive changes.

In the present protocol, *Takradhara* processed with *Amalaki* and *Yashtimadhu* was done externally for 2 weeks followed by *Abhyangam* with *Pinda Taila* mixed with *Vajraka Ghrita*. Adding of *Pinda Taila* with *Vajraka Ghrita* has special indication in psoriasis associated with arthritis. Internal administration of *Manibhadra Leha* has been advocated in *Kushta* (skin disease) and *Raktaja Vikara.* This acts like *Nitya Shodana* for the skin ailments. *Rasnaerandadi Kashaya* mixed with *Kaishora Guggulu* tablet has specific effect in treating psoriatic arthritis and widely

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used in Ayurvedic practice in Kerala. *Kaishora Guggulu* is specifically mentioned for *Kushta, Tridoshaja Vatarakta*. Use of *Vajraka Ghrita* internally at bedtime, also have significant action in *Raktapittaja* conditions and special indication in *Kushta* (skin disease). The *Asanavilwadi Taila* was used for *Shiroabhyanga* which is generally prescribed for all the *Raktaja* and *Pittaja Vikara.*

The report of the laboratory investigations including liver and renal function tests were compared before and after treatment and observed that there is no significant difference in the values which is an indication of the safety of the treatment. There were no adverse drug reaction reported during the course of therapy.

CONCLUSION

The clinical study clearly indicates that the prescribed classical Ashtavaidyan Ayurveda line of treatment is effective in the management of psoriatic arthritis (*Vatarakta*). The treatment has shown significant improvement in the functional ability of the patients. Moreover, the biochemical parameters to evaluated the changes in liver and kidney function did not show any significant variations. This indicates that the therapy is safe without producing any complication or adverse drug reaction.

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