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ORIGINAL RESEARCH ARTICLE: CLINICAL RESEARCH

CLASSICAL ASHTAVAIDYAN AYURVEDIC THERAPY IN THE FUNCTIONAL IMPROVEMENT OF PATIENTS WITH ANKYLOSING SPONDYLITIS: AN OPEN LABEL, SINGLE ARM CLINICAL STUDY

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ABSTRACT

Background: Ankylosing spondylitis is a chronic, systemic, inflammatory disease that affects primarily the sacroiliac joints and spine with the symptoms of muscular spasm, stiffness and limitation of movement of spine. Traditional practice of Ashtavaidyan Ayurveda line of management has been tried to evaluate the efficacy in ankylosingspondylitis.A combined treatment with internal medication and external therapeutic procedures has been taken up to assess the evaluate the effect on the functional improvement and safety in ankylosing spondylitis. **Methodology:** Diagnosed cases of ankylosing spondylitis (n=30) (20-60 yrs) have undergone the prescribed classical Ashtavaidyan Ayurvedic therapy; the total study period was 57 days which included 21 days each at inpatient and outpatient basis and 15 days of follow up. Initially Pizhichil with KetakeemooladiTaila with PanchatiktakaGhrita was performed along with internal medications for first 7 days later same internal medication is continued with SathailaTila PindaSweda and followed by Panchatikthaka KsheeraBasti for last 7 days. Same internal medicines and oil application were continued for next 21 days on outpatient basis and BalaguluchyadiTaila was applied regularly on scalp for all these days. **Result:** The response of treatment was assessed periodically with respective parameters and was showed significant improvement. The functional improvement was evaluated by using the BASDAI score, DAS-28 score, disability index, SF-36 and global assessment of disease activity scale and there were significant changes in all the above scales. The laboratory parameters used to evaluate the liver and kidney functions did not show any significant change that indicates the prescribed treatment is safe. **Conclusion:** Traditional Ashtavaidyan Ayurveda therapy is s effective in improving functional ability in Vatarakta vis-à-vis ankylosingspondylitis over a period of 42 days. Moreover, there was no adverse drug reaction recorded during as well there was no significant change observed in liver and renal function tests.

Keywords: Ayurveda, ankylosingspondylitis, Vatarakta, Pizhichil, GandarvasthadiKashaya, Kethakeemooladi Taila, KsheeraBasthi, HLA-B27

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INTRODUCTION

Ankylosing spondylitis (AS) is an inflammatory disorder of unknown cause that primarily affects the sacroiliac joints and spine, which can progress to bony fusion of spine. The onset is typically between the ages of 20 -30, with a male preponderance of about 3:1[1].

The tendency to develop ankylosing spondylitis is believed to be genetically inherited, and majorities (nearly 90%) of people with ankylosing spondylitis are born with a gene known as the HLA-B27. The symptoms of the disease are usually first noticed in late adolescence or early adulthood. The initial symptom is usually dull pain, insidious in onset, felt deep in the lower lumbar or gluteal region, accompanied by low-back morning stiffness of up to a few hours duration that improves with activity and returns following periods of inactivity[2].

Common sites affected include the costosternal junctions, spinous processes, iliac crests, greater tronchenters, ischial tuberosities, tibial tubercles and heels. The most specific findings involve loss of spinal mobility (bamboo spine), with limitation of anterior and lateral flexion and extension of the lumbar spine and of chest expansion. Limitation of motion is usually out of proportion to the degree of bony ankylosis, reflecting muscle spasm secondary to pain and inflammation. Sacro-ilitis is usually one of the earliest manifestations of AS, with features of both enthesitis and synovitis. The enthesitis is associated with prominent oedema of the adjacent bone marrow and is often characterised by erosive lesions that eventually undergo ossification [3].

Ankylosing spodylitis may be included in the purview of *Vatarakta*. It is observed that, AS is said to have affected the hips and shoulders (root joints) in 25 to 35% of patients hence it may be referred as *Trikagraha* or at times *Katigraha* also.

On evaluation of the *Dosha* - *dushya* involvement in this disease, it may be seen that primarily *Vata* along with *Asti, Mamsa, Majja Dhatus* are affected. The signs and symptoms of *Vatadhika Vatarakta* may be correlated to the features of AS. The features of vitiation of Vata such as dryness, stiffness and deformities are observed in the patients at various levels[4]. There may be *Avarana* of *Vata* at *Dhatu* level which may produce pain in hip, lumbo-sacral and spine (*Sroni Vamkshana Prishta Ruk*) as referred in the classical reference of *Sarvadhatvavruta Lakshanas*. As the condition progresses it may produces the cardinal symptoms of the disease, restriction of spinal movement, stiffness and deformities.

In the present condition, *Vatahara* measures along with regenerative effect to nourish the degenerated *dhatus* will be the line of management. So *Snigdha* and [*brumhana* [5]

type of treatment is generally advocated. The treatment principles of *Vatadhika Vatarakta* include *Snehapana, Abhyanga* and *Basti* with suitable formulations [6]. External unctuous applications usually prescribed are *Pizhichil, Shashtika Shali Pinda Sweda, Ksheerabasti* which are said to have *Vatahara* and *Brihmana* properties advocated for regeneration of the affected tissues.

Traditional practice of Ashtavaidyan line of management has been clinical evaluated to assess the efficacy in ankylosing spondylitis. In this study, a combined treatment with internal medications and external therapeutic procedures has been taken to evaluate the efficacy and safety. The course of treatment included *Pizhichil (Kayaseka)*with *Ketakeemooladi Taila*[7] with *Panchatiktaka Ghrita*[8] in 3:1 ratio, *Sataila Tila Pinda Sweda* and *panchatikthakaKsheeraBasti*[9] along with *Balaguluchyadi Taila*[10] for *Shirobhyanga*, while *Gandharvahastadi kashaya*[11] with *prakshepaka churna- Saindhava* and *Guda*- (powdered rock salt and jaggery), *Rasnasaptaka Kashaya*[12], *Lakshadi Guggulu*[13] were given.

M**ethodology:**

Research Design: The study was prospective, open label, single arm, single centered clinical study conducted at Vaidyaratnam Ayurveda Foundation Hospital, Ollur, Thrissur, Kerala. 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 trial program was approved by the Institutional Ethics Committee and the study was registered with Clinical Trial Registry of India (CTRI/2018/09/015819). 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.

Selection of Patients and Informed consent process: The patients attended with the clinical features of ankylosing spodylitis in the outpatient department of Vaidyaratnam Ayurveda Foundation Hospital, Thrissur were screened according to the inclusion criteria - early morning stiffness lasting more than one hour, pain and stiffness of the spine, reduced chest expansion, history of uveitis, positive HLAB-27 and pain in the sacroiliac joint and the age groups of patients selected were between 20-60 years. Exclusion criteria were patients who have developed secondary complications, steroid dependence, arthritis like gout, osteo-arthritis, Tubercular arthritis, Rheumatic fever, Gonorrhoeal / Syphilitic arthritis, Arthritis with malignancy, Acute pyogenic arthritis, Osteomyelitis . Poorly controlled hypertension / diabetes mellitus (type 2) and impaired cardiac, hepatic and renal function as well as pregnant and lactating women.

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.

FLOW CHART OF PATIENT RECRUITMENT

Tracing of the Trail participant from OPD / Referrals from the hospital

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Screening of the trail participant by clinical execution

↓

Issue of Patient Information sheet

↓

Counseling – I

↓

Signing of Informed consent form

↓

Referring for laboratory Investigations

↓

Laboratory screening and Instructions for next visit

↓

Filing up of case report form – I Screening

ENROLMENT DAY

Assessment at Baseline

↓

Recruitment of participant (if suitable)

↓

Filing up of case reports form – II A History of baseline

↓

Filing of CRF II B – Ayurvedic Parameter

↓

Admission for IP treatments

↓

Remainders for next follow up on 21st day

ASSESSEMENT ON 21ST DAY

Follow up on 21st day – After IP treatments

↓

Filing up of CRF – IV

↓

Clinical assessments after IP treatments

↓

Complete Assessments of laboratory investigations

↓

Notifying the concomitant medications, rescue medications and adverse reactions, if any

↓

Drug dispensing for 21 days of OP Treatments

↓

Instruction for OP visits& Reminders by phone/postcard/email

ASSESSEMENT ON 42nd DAY

Follow up visit on 42nd day- OP Medicines

↓

Filing of CRF - V

↓

Clinical assessments with Laboratory Investigations

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Notifying the concomitant medications, rescue medications and adverse reactions, if any

↓

Issue of remainders by Phone/ Email/ Post card before next visit

ASSESSEMENT ON 57th DAY

Follow up visit on 57th day- without medicines

↓

Filing up of CRF - VI

↓

Clinical assessments

Intervention:

Table 1: Medicines and treatment

Internal			***Days***		***External***		
Medicine	***Dose***	***Time***	***IP***	***OP***	***Procedure***	***Medicine***	***Days***
Gandharvastadi Kashaya with one pinch *Saindava*& 1/4tsp jaggery	100 ml	6am	21	21	*Pizhichil*	*Kethakeemooladi taila* 3part + *panchatiktha*	1 to 7 days (IP)
					Sathaila Tila pinda sweda		8to 14 days(IP)

Rasnasaptaka Kashaya with *Lakshadi Guggulu Gulika*	100ml + 1 tablet	6pm	21	21	*Panchatikthaka Ksheera Basti*	*ka Ghritha* 1part	last 7 days of IP
					Sirobhyangam	*Karapasthyadi Taila*	21 days (IP) + 21 days (OP)

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. *Gandharvastadi Kashaya* 100ml mixed with one pinch *Saindhava* and 1/4tsp jaggery at morning 6 am and *Rasnasaptaka Kashaya* with *Lakshadi Guggulu* tablet at evening 6 pm. Externally, from first7 days, *Pizhichil* (Kayaseka) with *Ketakeemooladi Taila* with *Panchatiktaka grita*. From day8 to 14 *Sathaila Tila Pinda Sweda* and from day 15th to 21, by *Panchatikthaka Ksheera Basti* and *Balaguluchyadi Taila* on scalps 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 which is GMP certified Ayurveda pharmacy.

Treatment assessment:

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 were performed for all the patients at baseline and after the full course of the treatment. This includes HLA-B27, haemogram, biochemical parameters namely blood glucose, serum cholesterol, uric acid, liver function tests, renal function tests, C-reactive protein and ASO titter and X-ray of affected joint was taken. The functional improvement was recorded using the validated scales - visual analogue pain rating scale, DAS score, SF-36, disability index and global assessment scale.

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

Socio-demographic Profile:

Table 2: Socio-Demographic Characteristics of the Patients

Characteristics	Category	Frequency	Percentage

Gender	Female	3	10.0
	Male	27	90.0
Occupation	Field work with physical labour	8	26.7
	Field work	4	13.3
	Desk Work	20	66.7
	Field work with physical labour	6	20.0
	Field work	3	10.0
	House wife	1	3.3
Habitat	Urabn	7	23.3
	Semi-urban	20	66.7
	Rural	3	10.0

Disease profile:

The majority of patients had an insidious onset (90%) and remaining 10 % was with acute onset. 10% of participants were having a recent onset with less than 6 months duration and the rest were between 24- 60 months interval. In 10% of participants there was a previous history of illness.

Result

Effect on joint parameters:

The assessment of chief complaints at the baseline of treatments were pain in joints (100%), swelling in joints (76.7%), spinal stiffness (100%) tenderness (90%) fever (16.7%), general weakness (86.7%), redness of eye (20%) , Pain in thoracic region(56.7%) and stiffness in thoracic region (60%). 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 thefirst periodical assessment itself. The statistical evaluations of the chief complaints such as pain, swelling, have got significant response with $P< 0.01$(Table 3).

Table 3 Comparison of joint complaints at different visits

Complaints	First day	21st Day	42nd Day	57th Day
Pain in Joints	30 (100)	16 (53.3)	12 (40.0)	11 (36.7)
Swelling in joints	23 (76.7)	2 (6.7)	0	0
Spinal Stiffness	30 (100)	21 (70.0)	23 (76.7)	20 (66.7)
Tenderness	27 (90.0)	8 (26.7)	3 (10.0)	2 (6.7)

Fever	5 (16.7)	0	0	0
Malaise/fatigue/weakness	26 (86.7)	2 (6.7)	1 (3.3)	0
Redness of eye	6(20.0)	1(3.3)	1(3.3)	1(3.3)
Pain in Thoracic region	17 (56.7)	7 (23.3)	8 (26.7)	6 (20.0)
Stiffness in Thoracic region	18 (60.0)	15(50.0)	11 (36.7)	9(30.0)

Values within brackets are percentages

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***
VAS Score	5.57 ± 0.22[a]	2.90 ± 0.23[b]	2.20 ± 0.26[c]	-	56.000**	< 0.001
Joints involved	18.00 ± 1.30	1.23± 0.49	-	-	13.88	< 0.001
DAS score	44.33 ± 2.18	71.0 ± 2.32	78.17 ± 2.67	-	145.101**	< 0.001
Disability index	1.170 ± 0.064[a]	0.412 ± 0.056[b]	0.243 ± 0.048[c]	0.196 ± 0.043[d]	125.480**	< 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 and 42nd day and found that there was a significant reduction in the number of the affected joints (P<0.001).

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 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 ankylsong spondylitis related parameters:

TABLE 6: Comparison of BASDAI Score

Dimensions	First day	21st day	42nd day	57th day	F-value	p-value
Fatigue/tiredness	6.27 ± 0.25	2.6 ± 0.33	1.13 ± 0.22	0.67 ± 0.2	176.828**	< 0.001
Neck/Back pain	7 ± 0.18	3.3 ± 0.27	2.17 ± 0.21	1.7 ± 0.16	275.043**	< 0.001
Swelling in joints	6.53 ± 0.24	2.7 ± 0.35	1.7 ± 0.24	1.27 ± 0.21	156.029**	< 0.001

Discomfort	7.1 ± 0.26	2.77 ± 0.31	1.7 ± 0.19	1.6 ± 0.19	170.362**	< 0.001
Level of morning stiffness	6.47 ± 0.23	2.8 ± 0.25	1.73 ± 0.2	1.43 ± 0.2	168.121**	< 0.001
Morning stiffness	6.5 ± 0.25	2.63 ± 0.22	1.63 ± 0.19	1.23 ± 0.18	185.914**	< 0.001

***- significant at 0.01 level*

The specific scoring method used for assessment of ankylsong spondylitis known as the BASDAI score. shows that when compared to the baseline observation with period of interval 21st ,42nd,and 57th day, a highly significant improvement was noted in all the symptoms, with P<0.001 (Table 6).

Biochemical parameters:

The biochemical and hematological parameters namely ESR, CRP, Hb% renal and liver functions 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 there no adverse effect in the body following the prescribed medications and therapy.

Table 6: Observation of Liver and Renal Function Tests

Parameters	Day 1	Day 21	Day 42	F-value	P-value
Blood urea	31.27 ± 0.96	25.23 ± 0.65	27.93 ± 0.92	18.851**	0.358
Uric Acid	4.48 ± 0.25	4.46 ± 0.2	4.48 ± 0.19	0.0146ns	0.806
Serum Creatinine	0.83 ± 0.02	0.81 ± 0.02	0.8 ± 0.02	0.812ns	0.504
SGOT	25.4 ± 1.58	26.3 ± 1.6	23.53 ± 1.66	2.307ns	0.014
SGPT	28.9 ± 2.07	25.43 ± 1.65	28.03 ± 1.93	2.116ns	0.166
Total Protein	7.64 ± 0.13	7.45 ± 0.11	7.6 ± 0.09	1.122ns	0.962
S. Albumin	4.04 ± 0.06	4.02 ± 0.06	4.16 ± 0.04	4.008*	0.023
S. Globulin	4.01 ± 0.5	3.93 ± 0.49	3.77 ± 0.33	0.961ns	0.372
S. Bilurubin	0.74 ± 0.05	0.82 ± 0.06	0.78 ± 0.05	2.545ns	0.087
S. alkaline Phosphates	176.87 ± 10.63	169.67 ± 10.05	180.9 ± 12.45	0.807s	0.426

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

DISCUSSION:

As described earlier ankylsong spondylitis can be compared with *Vatarakta* where restriction of movement and stiffness of spine, hip and shoulder girdle are the cardinal features. The Ashtavaidyan Ayurvedic line of

treatment for the disease has been formulated according to the *Dosha* involvement.

The data derived from the statistical assessment of the response of the therapy clearly indicate that the prescribed method of management have highly significant in the management of ankylosing spondylitis. The statistical analysis of the effect of the treatment has shown significant improvement in the functional ability of the patients also.

Effectiveness:

As discussed earlier, the symptoms and pathogenesis of ankylosing spondylitis have similarities to the descriptions of *Vatadika Vatarakta* in Ayurveda. It is related with lifestyle of the person who indulges in improper ways of dietary, physical and mental activities that vitiate *Vata, Pitta* and *Rakta*. In this clinical study, the traditional practice of Ashtavaidyan line of management has been tried to evaluate the effectiveness in ankylosing spondylitis. Keeping in view of the pathogenesis with respect to *Dosha Dushya* involvement in AS, *Vatahara* treatment focused on *Snigda* and *Brumhana* in nature are to be prescribed. The course of treatment included *Pizhichil, Tila Pottali Sweda* with *Ketakeemooladi Taila* with *Panchatiktaka Ghrita* and *Panchatikthaka Ksheera basti* and *Balaguluchyadi Taila* for *Shirobhyanga*. *Gandharvasthadi Kashaya, Rasnasaptaka Kashaya* with *Lakshadi Guggulu Gulika* were given internally.

Pizhichil, Tila Pottali Sweda and *Panchatikthaka Ksheera basti* might have contributed to reduce the stiffness and strengthen the muscles associated with the clinical condition. The oil *Kethakeemooladi taila* has special reference to *Asthigata vata* and *Panchatiktha Ghrita* is V*ata Pitta Samana and* is useful for the regeneration of bone tissue and nourishes the joints. The *Ksheera basti* helps in nourishing the *Dhatus*, strengthens the bones, due to Ushna and Snigdha Guna, it removes the Ruksha and Sthamba Guna of Vayu there by restrict the fusion of joints.

Among the internal medicines *Gandharvahasthadi Kashaya* will be useful in pacifying the vitiated *Vata* due to its *Anuloma Guna* especially *Kati Pradesha* (lumbosacral area) that relieves the pain and stiffness. *Rasnasapthakam Kashaya* has special reference to reduce the inflammation and relief of pain in lumbo-sacral part and lower limbs. *Lakshadi Gulgulu* helps in strengthening of bones and to increase the bone density due to its binding property.

CONCLUSION

Tradition Ashtavaidyan Ayurveda therapy is found effective in functional improvement of patients of ankylosing spondylitis over a period of 42 days. . Moreover, there was no adverse drug reaction recorded during as well there was no significant change observed in liver and renal function tests. This indicates that the

therapy is safe without producing any complication.

Conflict of interest: None

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