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CLINICAL EVALUATION OF THE EFFECT OF TIKTA KSHIRA VASTI AND PATRA PAUTTALI SWEDA ALONG WITH SAMANAUSHADHI IN THE MANAGEMENT OF ANKYLOSING SPONDYLITIS

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ABSTRACT

Ankylosing Spondylitis (AS) is a complex and potentially debilitating disease with insidious onset where there is inflammatory arthritis affecting the axial skeleton. The pathogenesis of AS is poorly understood. However, immune mediated mechanisms involving human leucocyte antigen (HLA) – B27, inflammatory cellular infiltrates, cytokines (for example, tumour necrosis factor α and interleukin 10) and genetic and environmental factors are thought to have key roles. Non-steroidal anti-inflammatory drugs (NSAIDs) are the first line of treatment to relieve the pain and on the other hand second line treatments includes corticosteroids and Disease Modifying Anti Rheumatic Drugs (DMARDs) but are with limited benefit and give lots of complications on prolong use. If we look from the Ayurvedic point of view Ankylosing Spondylitis seems to be a disease of predominantly vataja origin where mainly asthivaha srota dusti takes place. According to Ayurveda Tikta Kshira and tikta ghrita vasti is considered as the line of treatment in the diseases caused by asthivaha srota dusti. As the disease is of vatic origin and inflammatory in nature, so it may be considered as an indication of Patra pauttali Sweda. In the present single blind clinical study with pre-test and post-test design, 12 patients suffering from Ankylosing Spondylitis has been selected after initial screening and Tikta Kshira vasti and Patra pauttali swedana was administered for 14 days uninterruptedly. Trayodashanga guggulu as Samana ausadhi was given throughout the treatment period and follow – up period. Patients were observed for a total follow-up period of two months with assessment on 0 day 30th day and 60th day. The assessment of results was made by adopting the standard methods of international scoring (like- Bath Ankylosing Spondylitis Functional Index, Bath Ankylosing Spondylitis – Disease Activity Index, and Ankylosing Spondylitis Quality of Life Questionnaire). After statistical evaluation significant improvement was observed in the parameters which indicate the effectiveness of Tikta Kshira vasti and Patra pauttali swedana in the management of Ankylosing Spondylitis.

Key words: *Ankylosing Spondylitis, Asthivaha srota, Tikta Kshira vasti, Patra pauttali sweda, Trayodashanga guggulu.*

INTRODUCTION

Ankylosing spondylitis (AS) is a complex and debilitating disease with a worldwide prevalence ranging up to 0.9%. AS is the prototype of the spondyloarthropathies and one of the common rheumatic diseases. The aetiology and pathogenesis of AS is poorly understood. Immune mediated mechanisms are suggested by inflamma-

tory histology, raised serum levels of IgA and acute phase reactants, and the close relationship between HLA-B27 and AS. No single agent or event has been identified as the cause of the disease, but the interrelationship between AS, Reactive arthritis and Inflammatory Bowel Disease (IBD) suggests that enteric bacteria may play a part.[2, 3] Sacroiliitis is the earliest recognised manifestation of AS, but peripheral joints and extra-articular structures may also be affected. Subchondral tissues become granulomatous and infiltrated with plasma cells, lymphocytes, mast cells, macrophages, and chondrocytes. The affected joints show irregular erosion and sclerosis. Tissue is gradually replaced by fibrocartilage and then becomes ossified. When these lesions occur in the spine, the junction of the annulus fibrosus of the disc cartilage and the margin of the vertebral bone undergo irreversible damage. The outer annular fibres are replaced by bone and the vertebrae become fused. In advanced stages of the disease the fusion typically ascends the spine, forming a long bony column referred to as "bamboo spine".[4]

AS commonly starts in the second or third decade of life.[5, 6] Men are afflicted with AS approximately two to three times more frequently than women.[7] The disease pattern varies by sex.[8, 9, 10] The spine and pelvis are most commonly affected in men, with some involvement of the chest wall, hips, shoulders, and feet. In contrast, women have less severe involvement of the spine, with more symptoms in the knees, wrists, ankles, hips, and pelvis.[8, 9, 10] Disease also tends to be more severe in men.[9]

The first symptoms of AS usually appear in late adolescence or early adulthood. The initial symptom is typically a dull pain that is insidious in onset. The pain is generally felt deep in the buttock and/or in the lower lumbar regions and is accompanied by morning stiffness in the same area that lasts for a few hours, improves with activity, and returns with inactivity. The pain becomes persistent and bilateral within a few months and is usually worse at night. For some patients, bone tenderness may be the primary complaint or may accompany back pain or stiffness. Arthritis in the hips and shoulders occurs in some patients, often early in the course of the disease. Asymmetric arthritis of other joints, predominantly of the lower limbs, can be present at any stage of the disease. Neck pain and stiffness is characteristic of advanced disease. There are several extra-articular manifestations of AS, the most common condition being acute anterior uveitis. Patients may present with unilateral pain, photophobia, and increased lacrimation. Up to 60% of patients with AS have asymptomatic IBD.[11] In some cases, frank IBD will develop.[12] Aortic insufficiency, with possible congestive heart failure, is seen infrequently in patients with AS.[4]

Although no laboratory test is diagnostic of AS, the HLA-B27 gene is present in about 90–95% of patients with AS.[1] Only 50–70% of patients with active disease will have an increased level of C reactive protein (CRP) and a raised erythrocyte sedimentation rate (ESR).[13, 14, 15] However, measurement of the levels of these acute phase reactants appears to have limited value in determining disease activity.[14, 16] Studies have shown a lack of correlation between clinical signs of disease activity (pain, stiffness, and sleep disturbance) and CRP and ESR.[14] Mild normochromic normocytic anaemia may be detected. A raised alkaline phosphatase level may be

present in severe disease. Above normal serum IgA levels are common. Radiological changes reflect the disease process; thus, radiographic sacroiliitis usually becomes apparent at some point during the course of AS. However, many years of disease may pass before unequivocal sacroiliac changes are evident on radiographs. CT and MRI can detect AS lesions earlier and with greater consistency than plain radiography, but these methods are not routinely employed.[17]

On the basis of the 1984 modified New York criteria,[18] the diagnosis of AS can be made if radiological sacroiliitis (either grade II bilaterally, or grade III unilaterally) is present in conjunction with clinical signs (inflammatory back pain or restriction of spinal mobility).[18]

Table 1 : Modified New York Criteria for Ankylosing Spondylitis[18]

Radiologic criterion

- Sacroiliitis, grade - II bilaterally or grade III to IV unilaterally

Clinical criteria

- Low back pain and stiffness for more than 3 months that improves with exercise but is not relieved by rest.
- Limitation of motion of the lumbar spine in both the sagittal and frontal planes.
- Limitation of chest expansion relative to normal values correlated for age and sex.

Note: The condition is definitely AS if the radiological criterion is associated with at least one clinical criterion.

As it is a long standing disabling condition, it gives rise to many complications. The most serious complication encountered in AS is spinal fracture. Even minor trauma to the rigid, fragile spinal column can cause severe damage. The cervical spine is the most susceptible site; fractures at this site can result in quadriplegia. Prostatitis is highly prevalent among men with AS. Aortic insufficiency and cardiac conduction disturbances can occur in patients with long term disease. Amyloidosis, cauda equina syndrome, and pulmonary fibrosis are rare complications.[4]

Though this disease is not very uncommon and also causes deformities and disabilities resulting in poor quality of life, but no satisfactory treatment is available in the contemporary medical science. As a result patients of AS and other rheumatic conditions often take help of alternative and complementary medicine.[19 - 23] In a study it was found that more than 50% of patients with ankylosing spondylitis take consultation from the practitioners of traditional health care systems like Ayurveda.[24] This indicates the comparative efficacy of these health care systems in such conditions. Analysing the features of Ankylosing Spondylitis, it seems to be a Vata predominant disorder involving mainly the Asthi dhatu and Asthi vaha srota. In the diseases of Vata, Vasti is said to be the best treatment[25] and in the disorders involving the Asthivaha srotas Tikta Kshira and ghrita siddha vasti is specifically indicated.[26] So for the management of AS Tikta Kshira vasti is selected as the main treatment procedure. On the other hand in the diseases of vata snigdha swedana is specifically indicated and snehana followed by swedana is praised for its superiority in relieving stiffness and associated deformities.[27, 28] Among different varieties of swedana, Patra pauttali sweda is said to be very effective in pain, related to arthropathies.[29] So in the present study

Patrapauttali sweda has been selected with

MATERIALS AND METHODS:

Ingredients of Tikta Kshira vasti:

- *Makshik – 100 ml*
- *Saindhava – 2 gm*
- *Panchatikta guggulu ghrita – 150 ml*
- *Kalka (pancha tikta kalka) – 50 gm*
- *Pancha tikta Kshira paka – 200ml*

Ingredients for patra pauttali sweda:

Small pieces of the following leaves total 600 gm – *Eranda (Ricinus communis), Nirgundi (Vitex nigundo), Arka (Calotropis procera), Dhatura (Datura metal), Shobhanjana ((Moringa olifera), Chincha (Tamarind indica)*

Churna of the following drugs 10 gm each -Haridra (Curcuma longa), Methika (Trigonella foenum-graecum), Shatapuspa (Anethum sowa), Saindhava (Rock salt)

- Sliced lemon (Citrus limon) – 6
- Tila taila : to fry the leaves, for heating the pauttalis and for abhyanga - QS
- Cotton cloth piece (45cm x 45 cm) : to make the pauttali – 2

Samana ausadhi: Trayodashanga guggulu 250 mg thrice daily after food with hot water.

METHODS:

Drug preparation and administration:

Preparation of vasti dravya and its administration, procedure of Patrapauttali Sweda and preparation of Trayodashanga guggulu – all were done according to classical references.

Source of data: The patients attending the OPD and IPD of Panchakarma department, Govt. Ayurvedic College Hospital, Guwahati were screened and registered for the study after fulfilling the inclusion and exclusion criteria.

A detailed history taking and physical examination were carried out in these patients. The clinical data along with the elaborated assessment questionnaires of Vasti.

pain, back stiffness, functional ability and functional disability were recorded in the specially designed case proforma.

Inclusion criteria:

- Age between18 to 60 years.
- Patients fulfilling the diagnostic criteria of Ankylosing Spondylitis

Exclusion criteria:

- Diabetes mellitus
- Severe metabolic disorders
- Hypertension
- Psychiatric disorder
- Malignancy
- Epilepsy and
- Other diseases that needs regular medication
- Chronicity more than 10 years
- Ankylosing Spondylitis with severe disabling deformities

Diagnostic criteria :

Diagnosis was made on the basis of the 1984 modified New York criteria.[18] Diagnosis of Ankylosing Spondylitis was made in the presence of radiologically evident sacroiliitis (either grade II bilaterally, or grade III unilaterally) in conjunction with clinical signs (inflammatory back pain or restriction of spinal mobility) as shown in table-1.

Investigations:

Hemogram, selective biochemical tests including Blood Sugar Levels (Fasting and PP), Liver Function Test, Renal Function Test; C - Reactive Protein, R A Factor, ASO Titre, HLA – B27, X- Ray of the Pelvis Anteroposterior view to visualize the Sacroiliac joints was done and Plain X-Ray of the cervical, dorsal and Lumbo-sacral spine in Anteroposterior (AP) and Lateral views were carried out in selected patients according to need before treatment to exclude other conditions and to know about the severity of the disease.

Assessment criteria:

Patients were observed for two months. Assessment was done initially on '0' day i.e., before the medical intervention, after the completion of one month and after the completion of two months. Assessment was done based on the improvement in the severity of Clinical features along with the standard international parameters specially designed for assessing the outcome of the management of Ankylosing Spondylitis like-

- Bath Ankylosing Spondylitis Functional Index (BASFI)
- Bath Ankylosing Spondylitis – Disease Activity Index (BASDAI)
- Ankylosing Spondylitis Quality of Life Questionnaire (AS QoL Questionnaire)
- **Statistical analysis:** Statistical significance test was performed by Paired t-test. Graph Pad In Stat software was used for Statistical Analysis.

RESULTS: The assessment of results was made by grading the clinical features depending on their severity and by adopting the standard international scoring methods.

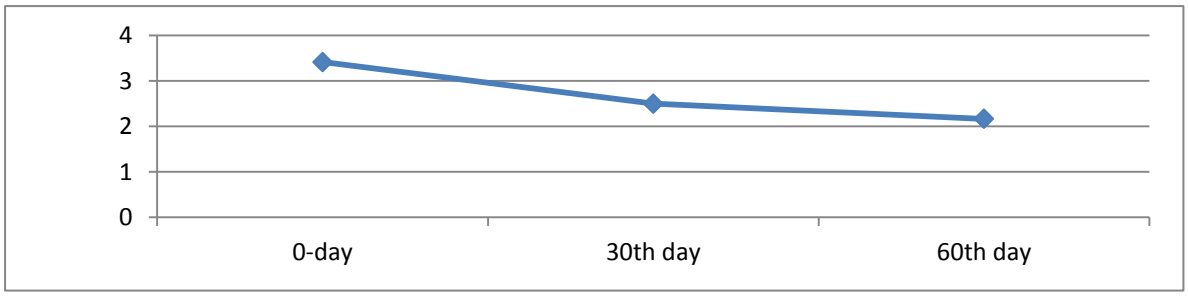
1. **Effect of treatment in terms of Pain relief:** The effect of treatment in terms of Pain relief on the 30th day was very significant and on the 60th day was also highly significant.

Table 2 : Effect of treatment in terms of Pain relief on the 30th day

MEAN ± SD		MD	P value	Remark
0 - Day	30th - Day			
3.417±0.6686	2.5±0.6742	0.9167	P<0.01	*

Table 3: Effect of treatment in terms of Pain relief on the 60th day

MEAN ± SD		MD	P value	Remark
0 - Day	60th - Day			
3.417±0.6686	2.167±0.7177	1.25	P<0.001	**



Graph-1: Reduction in the Pain score after treatment

2. **Effect of treatment in terms of relief of the back stiffness:** The effect of treatment in terms of relief of the Back stiffness on the 30th day was very significant and on the 60th day was also significant.

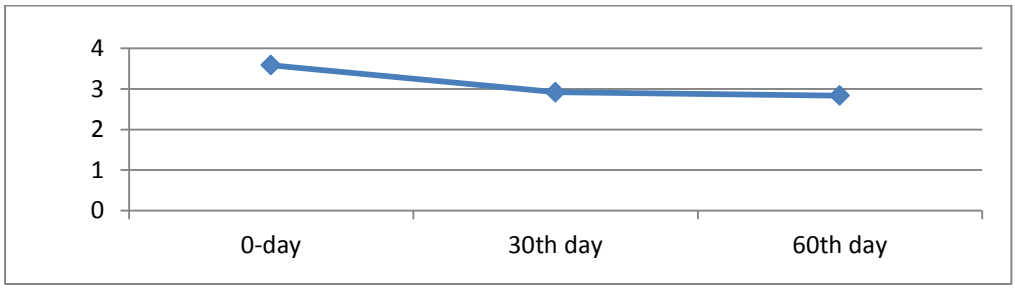
Table 4: Effect of treatment in terms of relief of the back stiffness on the 30th day

MEAN ± SD		MD	P value	Remark
0 - Day	30th - Day			
3.583±0.5149	2.917±0.5149	0.6667	P<0.01	*

Table 5: Effect of treatment in terms of relief of the back stiffness on the 60th day

MEAN ± SD		MD	P value	Remark
0 - Day	60th - Day			

3.583±0.5149	2.833±0.7177	0.750	P<0.05	*



Graph-2: Reduction in the back stiffness score after treatment

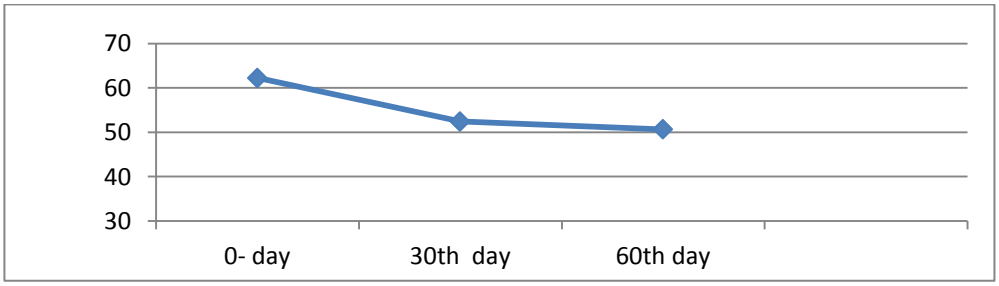
3. **Effect of treatment on Bath Ankylosing Spondylitis Functional Index (BASFI) Score:** The effect of treatment on the Bath Ankylosing Spondylitis Functional Index (BASFI) Score after the treatment on the 30th day and 60th day was very significant.

Table 6: Effect of treatment in terms of Bath Ankylosing Spondylitis Functional Index (BASFI) score on 30th day

MEAN ± SD		MD	P value	Remark
0 - Day	30th - Day			
62.25±8.561	52.417±12.295	9.833	P<0.01	*

Table 7: Effect of treatment in terms of Bath Ankylosing Spondylitis Functional Index (BASFI) score on 60th day

MEAN ± SD		MD	P value	Remark
0 - Day	60th - Day			
62.25±8.561	50.667±12.644	11.583	P<0.01	*



Graph-3: Effect of treatment on Bath Ankylosing Spondylitis Functional Index (BASFI) Score

4. **Effect of treatment on Bath Ankylosing Spondylitis – Disease Activity Index (BASDAI):** The effect of treatment on the Bath Ankylosing Spondylitis – Disease Activity Index (BASDAI) Score after the treatment on the 30th day and 60th day was highly significant.

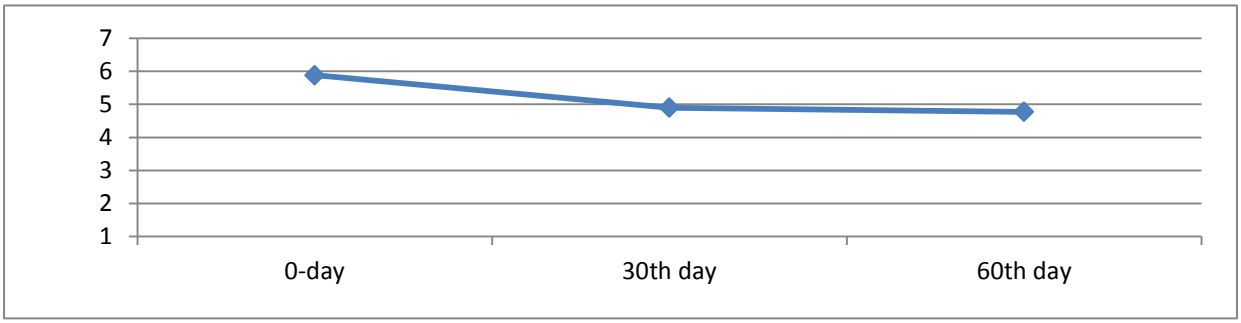
Table 8: Effect of treatment in terms of Bath Ankylosing Spondylitis – Disease Activity Index (BASDAI) score on 30th day

MEAN ± SD		MD	P value	Remark
0 - Day	30th - Day			
5.883±0.8953	4.9±1.103	0.9833	P<0.0001	***

Table 9: Effect of treatment in terms of Bath Ankylosing

Spondylitis – Disease Activity Index (BASDAI) score on 60th day

MEAN ± SD		MD	P value	Remark
0 - Day	60th - Day			
5.883±0.8953	4.775±1.052	1.108	P<0.0001	***



Graph-4: Effect of treatment on Bath Ankylosing Spondylitis– Disease Activity Index (BASDAI)

5. Effect of treatment on Ankylosing Spondylitis Quality of Life Questionnaire Score:

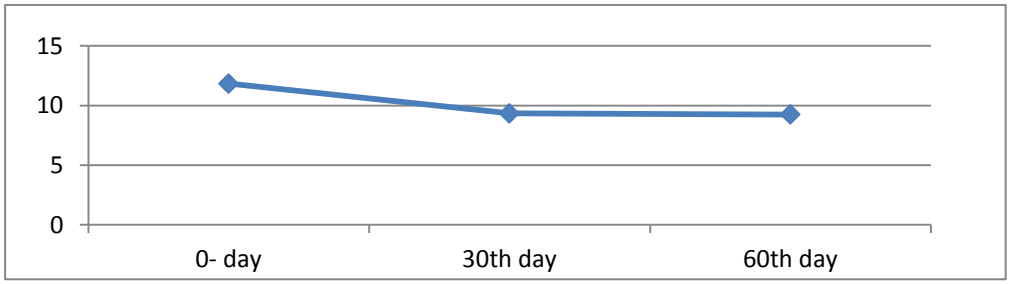
The effect of treatment on the 'Ankylosing Spondylitis Quality of Life Questionnaire' Score after the treatment on the 30th day and 60th day was highly significant.

Table 10: Effect of treatment in terms of Ankylosing Spondylitis Quality of Life Questionnaire score on 30th day

MEAN ± SD		MD	P value	Remark
0 - Day	30th - Day			
11.833±2.038	9.333 ±1.969	2.50	P<0.0001	***

Table 11: Effect of treatment in terms of Ankylosing Spondylitis Quality of Life Questionnaire score on 60th day

MEAN ± SD		MD	P value	Remark
0 - Day	60th - Day			
11.833±2.038	9.25 ±2.137	2.583	P<0.0001	***



Graph-5: Effect of treatment on Ankylosing Spondylitis Quality of Life Questionnaire Score

CONCLUSION:

In the present study 12 people, all of whom were males suffering from Ankylosing Spondylitis were treated with Tiktakshira vasti, Patra pauttali sweda along with Samana ausadhi. Patients were followed for a total period of two months. Significant relief of symptoms was observed during the follow up period. So it can be concluded that this treatment modality is effective in the management of Ankylosing Spondylitis. In this study as the sample size is very small, so similar study with a big sample size is needed to

establish this treatment modality in the management of Ankylosing Spondylitis.

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