ORIGINAL RESEARCH PAPER

Volume-8 | Issue-5 | May-2019 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

# DOES SUPERVISED REHABILITATION PROGRAMME ALTER DISEASE ACTIVITY IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS? –A RANDOMIZED CONTROLLED TRIAL.

Medical Science

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## ABSTRACT

Axial Spondyloarthritis (Ax-spA) is a group of chronic inflammatory diseases sharing common clinical & genetic features, involving axial skeleton, typical extra-articular manifestations and association with HLA B27 antigen. Rehabilitation programmes are gaining importance in those patients. A concurrent parallel randomized controlled trial was done to assess the change in Disease activity following a structured Supervised Rehabilitation Programme (SRP) with minimum pharmacological intervention on 60 axial spondyloarthritis patients, aged 18-45years, randomly allocated in two groups. Participants of intervention group were undergone SRP & control group were put on home exercise programme for 3 months. Disease activity was measured by Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). collected data analyzed with SPSS version20. BASDAI improved significantly in both groups after 3 months, whereas, intergroup analysis showed a significant improvement ($p<0.001$) in the intervention group undergone supervised rehabilitation programme compared to the control group. So SRP alters the disease activity in the study participants.

## KEYWORDS

Axial Spondyloarthritis, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Supervised Rehabilitation Programme (SRP).

### Introduction

Spondyloarthritis (SpA) is a group of chronic inflammatory diseases of autoimmune nature, sharing common clinical & genetic features, such as involvement of axial skeleton (sacroiliac joints & spine), certain pattern of peripheral joint involvement (usually asymmetric monoarthritis or oligoarthritis), presence of enthesitis, dactylitis, extra articular manifestations such as acute anterior uveitis, psoriasis, & inflammatory bowel diseases and association with HLA B27 antigen[1,2].

Axial Spondyloarthritis (Ax-SpA) is characterized by predominant involvement of spine & sacroiliac joints. Ax-SpA is defined in a comprehensive way by the classification criteria (ASAS)developed by Assessment of SpondyloArthritis International society [3].

Being a disease for which no permanent cure is known yet, long term anti-inflammatory drugs, disease modifying agents & biologics are generally used to control disease activity in those patients. Therapeutic costs along with adverse effects of these pharmaceutical agents are matter of concern. So, rehabilitation is the mainstay of management besides pharmacological managements [4,5]. The main aims of rehabilitation programme are maintaining corrective posture & joint Functions, coordination of movements & improving the respiratory functions. So reduction in spinal pain, stiffness, fatigue, and improvement in spinal mobility, as well as control over disease activity parameters can be achieved[6,7].

Studies were done in recent years to evaluate the improvement in disability parameters, using different modalities of rehabilitation programme. The Cochrane musculoskeletal group review suggested that an Individual home based or supervised exercise programme is better than no intervention & supervised group physiotherapy is better than home exercise [8]. In reality most of the studies were of variable duration of intervention, lacks standardized multidisciplinary institutional approach, ends in variable outcomes. So a structured supervised rehabilitation programme with all the necessary multidisciplinary components & least pharmacological interventions, for a convincing duration of 3months, was planned, for the patients with axial spondyloarthritis. A randomized controlled trial was done on these patients to test whether the supervised rehabilitation programme can make a significant difference in disease activity measured by Bath Ankylosing Spondylitis Disease activity Index (BASDAI).

### Subjects & Methods.

A concurrent parallel randomized controlled trial was done at the Department of Physical Medicine and Rehabilitation, R.G.Kar Medical College, Kolkata, during June 2014 to July 2015 with approval from the institutional ethics committee. Total 63 participants,(53male,10 female) diagnosed as axial spondyloarthritis [3], within the age group 18years to 45years were included in the study with exclusion criteria of active non-inflammatory spinal disease, Hip & Knee deformities, surgical history on Axial skeleton or peripheral Joints, Hypertension, Diabetes, Psychiatric illness, Heart Diseases, equilibrium disturbances & pregnancy. Participants were counseled about the study, relevance of rehabilitation & explained about the chances of first allocation in the in the supervised rehabilitation programme (intervention) group or home exercise (control) group, followed by signing the informed consent form (in the language he or she comfortable with). The participants were randomly allocated in two groups by serially numbered opaque concealed envelope technique. Total 32 participants allocated in intervention group & 31 participants in control group. The participants of intervention group were undergone supervised multidisciplinary rehabilitation programme including multimodal exercises[9] for 3 months at the dept. of Physical Medicine &Rehabilitation, R.G.Kar Medical College & Hospital, Participants of control group were demonstrated multimodal home exercises for a period of initial 3months (The interventions summarized in Table-1A & 1B).

*Table-1A:Interventions done*

| Supervised Rehabilitation Programme | Home Exercise Programme |
|---|---|
| • Supervised Multimodal Exercises thrice weekly,<br>• Aggressive Lifestyle Modification with regular supervision thrice weekly,<br>• Group therapy classes thrice weekly,<br>• Counselling weekly,<br>• Supervised Joint protection Technique weekly,<br>• Supervised Energy Conservation Technique weekly,<br>• Active Environmental modification weekly,<br>• Cognitive Behavioural Therapy for pain management weekly follow up session,<br>• Physical modalities for Pain management as required. | • Multimodal Exercise Programme demonstrated monthly,<br>• Lifestyle modification advises monthly,<br>• counselling monthly,<br>• Environmental modification advises monthly,<br>• Joint protection advises monthly,<br>• Energy conservation advises monthly.<br>• Physical Modalities for Pain management in Outpatient basis as required. |

**Table-1B; Descriptions of The multimodal exercise program for Spondyloarthritis[9].**

**1. Warm-up**: 10 minutes of step exercises (each motion repeated 10 times) + 5 minutes of stretching exercises.
**2. Main period**: 20 minutes of step exercises (each motion repeated 10 times).
**3. Cool-down:** 10 minutes of pulmonary exercises + 5 minutes of stretching exercises.

| Step Aerobic Exercises | Stretching Exercises |
|---|---|
| 1. March<br>2.Tap up-tap down<br>3.V step<br>4.Step touch<br>5.Turn step<br>6.Grapevine<br>7.Grapevine with knee up<br>8.Grapevine with leg curl | 1. Forward and backward head stretch.<br>2. Sideways head stretch.<br>3. Chest and shoulders stretch.<br>4. Deltoid muscle stretch.<br>5. Triceps muscle stretch.<br>6. Overhead stretch.<br>7. Lateral trunk muscle stretch.<br>8. Arched back stretch.<br>9. Leg extensor and pelvic flexor stretch.<br>10.Spinal twist stretch.<br>11.Para vertebral muscle stretch.<br>12. Loosen-up stretch.<br>13. Upper back prayer.<br>14. Double knee-to-chest stretch. |
| **Pulmonary Exercises** | |
| 1. Deep breathing, Diaphragmatic breathing, Fast breathing Exercises.<br>2. Resistance exercises for the inspiratory pulmonary muscles. | |

After 3 months, participants of control group were invited in supervised rehabilitation programme, so that they should not be deprived. All the participants didn't have any history of DMARDs or Biologic therapy before & during study period. Short course of Non Steroidal Anti inflammatory drugs were used not more than two times during the 3 months period of rehabilitation (as and when required). No local or systemic steroid drug was used during study period.

In this study, disease activity was measured by Bath Ankylosing Spondylitis Disease activity Index (BASDAI), which consists of 6 questions (related to arthritis, enthesitis, spinal pain, and fatigue & morning stiffness) to be answered in numerical rating scale of 0 to 10, averaged with a specific equation. A decrease in BASDAI score was recorded as improvement[3,5]. The data collected from the two groups will be compiled in Microsoft Office Excel 7 & analyzed with SPSS version 20 to obtain respective conclusions.

**Results.**

Data were collected in the specified format at the time of entering the study (baseline) & the end of study (i.e. after 3 months) from both groups. The baseline data collected from drop outs (2 from intervention group & 1 from control group) were not included in analysis. After drop out exclusion, each group had 30 participants (male 25, female 5). Adherence to the supervised rehabilitation programme by participants of intervention group was 66% or more.

Data analyzed by SPSS version 20. Variables were tested for normal distribution by Shapiro-wilk test. Then the appropriate test of significance used. Discrete variables were analyzed by Chi Square tests. Continuous variables were analyzed by either appropriate paired/unpaired T-test (for normal distribution) or, non-parametric Mann- Whitney U test (for skewed distribution).

p value less than 0.05 is taken as statistical significant change.
Baseline characteristics in both groups were similar (vide Table-2).

***Table-2; comparison in Baseline characteristics between two groups***

| Parameters | Intervention group(n=30) (Mean± SD) | Control group (n=30) (Mean± SD) | *p value* |
|---|---|---|---|
| Age (yrs) | 29.7±7.15 | 28.34±6.99 | 0.457* |
| Completed years of Education (yrs) | 10.17±4.51 | 9.5±4.11 | 0.50† |
| Body Mass Index (BMI) ($Kg/m^2$) | 23.51±3.31 | 23.35±3.52 | 0.929† |
| Duration of low back pain (LBP) (months) | 39.33±30.32 | 39.13±35.76 | 0.761† |
| BASDAI | 4.24±1.2 | 3.96±1.1 | 0.332† |

*Two tailed unpaired t-test.
†Mann- Whitney U tests.
SD=Standard deviation.
BASDAI =Bath Ankylosing Spondylitis Disease Activity Index

After 3 months rehabilitation, data from study variables in both groups analyzed. The result of the post intervention outcome analysis is shown in table-3.

***Table-3: Effects of Supervised Rehabilitation Programme in respect of Disease Activity (measured by BASDAI).***

| Variables | Intervention Group (n=30) | | | Control Group (n=30) | | | Differences between outcome in two groups |
|---|---|---|---|---|---|---|---|
| | Baseline (Mean ±SD) | 3months (Mean ±SD) | *p-value* | Baseline (Mean ±SD) | 3months (Mean ±SD) | *p-value* | *p-value* |
| BASDAI | 4.24±1.2 | 1.42±0.52 | <0.001 | 3.96±1.1 | 2.74±0.88 | <0.001 | <0.001 |

As data were not distributed normally, non-parametric Mann-Whitney U test was used.
SD=Standard deviation.
BASDAI= Bath Ankylosing Spondylitis Disease Activity Index.

There was no significant difference ($p$=0.332) in baseline distribution of BASDAI score in participants between both groups. Significant improvement observed in BASDAI score in both intervention ($p$<0.001) & control group ($p$<0.001) after 3 months. Upon intergroup analysis, participants of Intervention group undergone supervised rehabilitation programme had significant reduction in BASDAI ($p$<0.001) compared to the participants of control group.

**Discussion;**

Supervised rehabilitation programme (SRP) is a comprehensive rehabilitation programme for patients with Axial spondyloarthritis, organized as group therapy sessions consists of patient education, lifestyle modification, postural control, joint protection, energy conservation techniques, along with the multimodal exercise programme[10]. SRP also includes Cognitive behavioral Therapy sessions (as and when required) to improve pain coping skills. Multimodal exercise programme consists of total 50minutes of aerobic, stretching & pulmonary exercises, which restores joint mobility, prevents and corrects deformities, relieves pain, and improves physical endurance. In this study, disease activity was measured with Bath Ankylosing Spondylitis Disease activity Index (BASDAI). Even if the BASDAI does not include a biomarker of inflammation, studies have shown that this measure is highly correlated with the new Ankylosing Spondylitis Disease Activity Score (ASDAS), which includes inflammatory markers[11,12].

There was no significant difference ($p$=0.332) in baseline distribution of BASDAI score in participants between both groups. Significant improvement observed in BASDAI score in both intervention ($p$<0.001) & control group ($p$<0.001) after 3 months. Upon intergroup analysis, supervised rehabilitation programme showed significant superior effect in reduction of disease activity ($p$<0.001) than the control group.

Similar duration studies showed more or less similar outcome. Silje Halvorsen Sveaas et al [13], showed significant improvement in BASDAI with High intensity supervised endurance & strength exercise. Whereas Meryem Özbaş Günay et al.[14] reported significant improvement in BASDAI within the study group undergone breathing & posture exercises. Yndis A. Staalesen Strumse et al. [15] recorded significant improvement in BASDAI score after 4 weeks of rehabilitation in both exercise groups, whereas Mediterranean group had reported significantly higher improvement in disease activity than the other group. Short term in-patent supervised rehabilitation programmes done by Siv Grødal Eppeland et al.[16] and Ingvild Kjeken et al.[17] showed significant improvements in BASDAI in their study population. Whereas S. Berea et al. failed to register any significant difference in BASDAI with short term Pilate method[18].

From the different studies, it was evident that most of the rehabilitation programme documented significant improvement in disease activity measured by BASDAI, which is comparable with this present study on the patients with Axial Spondyloarthritis undergone supervised rehabilitation programme.

According to Lubrano et al. [19], rehabilitation was superior to anti-TNFα therapy alone, for improvements in anthropometric measures. Therefore, supervised rehabilitation programme may be a substantial supplementation to pharmacological management in order to improve mobility & disease activity in patients with Spondyloarthropathy. Warm and stable climatic conditions may enhance capacity of rheumatic patients to perform physical exercises [20], and this might

explain why the improvements were larger when the rehabilitation was performed in a tropical climate setting like eastern India.

So, this rehabilitation programme may be cost-effective, accessible & acceptable alternatives to drugs with multiple adverse effects (mainly biologics & DMARDS) in patients with Axial Spondyloarthritis. This can also be the only effective management in patients with contraindications to biologics & DMARDs.

**Conclusions:**

Disease activity measured by Bath Ankylosing Spondylitis Disease activity Index (BASDAI) improved significantly after the supervised rehabilitation programme in patients with Axial Spondyloarthritis.

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