ORIGINAL RESEARCH PAPER
Volume-9 | Issue-1 | January-2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

AN OUT PATIENT DEPARTMENT BASED INSTITUTIONAL PROSPECTIVE STUDY ON EVALUATION OF CHANGES OF FUNCTION ABILITIES IN PATIENTS WITH AXIAL SPONDYLOARTHROPATHY ON REHABILITATION IN THE NORTHERN DISTRICTS OF WEST BENGAL

Community Medicine

Dr. Swapan Kumar Mishra Associate Professor, Department of Physical Medicine & Rehabilitation North Bengal Medical College, Sushrutanagar, Darjeeling

Dr. Tushar Kanti Saha* Associate Professor, Department of Community Medicine; North Bengal Medical College, Sushrutanagar, Darjeeling *Corresponding Author

ABSTRACT

Introduction: AS is a disease of spinal enthesopathy with peripheral joints involvement, especially hip joint and shoulder joint, Knee and Ankle joints and enthesis of TA at Calcaneum occurs, leads to pain, stiffness along with gradually progressive deterioration of functional capacity of affected persons.

Aims and Objectives: Study designed to assess, evaluate, interpret and record changes on clinical and investigative parameters for 18 months in Northern part of West Bengal on cases of Axial Spondyloarthropathies under medical treatment in various clinical discipline (e.g. Medicine Orthopaedics and Rheumatology) those are referred to Physical Medicine and Rehabilitation (PMR) Clinic for rehabilitation care to improve their functional capacity.

Materials and Methods: Clinical scores like BASDAI, BASFI, 6-Min Walk Test was used to assess functional Capability of patients at entry level/baseline assessment and during follow-up periods. Moreover Pulmonary Function Test (PFT) assessed in both situation to evaluate the pulmonary Function of them. Total 76 patients included in study and recruitment process were continue for 06 months before initiation of the study and 06 Patient were unable continue till the end of the study due to personal reasons. Changes in BASDI Score and BASFI Scores vary with quality of initial of management by referred department and the status of the disease activities during initial reporting to the department.

Results: During result analysis that BASFI Score was improved from 3.37(+ 0.47) to 1.29 (+ 0.39) and BASDAI Score reduced from 6.03 (+ 0.37) to 3.53 (+ 0.23). There was statistically significant improvement in baseline to endpoint data in both BASDAI and BASFI. Maximum improvement noted in initial 6 months of rehabilitation programme at PMR Clinic in BASDAI Score and For BASFI Score best result noticed for initial 9 months of follow up.

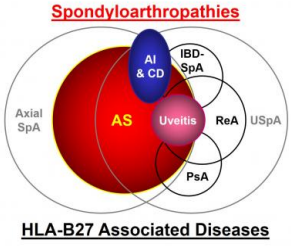
Conclusion: Base line Scores in BASDI and BASDI in clinical evaluation and Vital Capacity (VC) and FEV1 in PFT was mostly noted with positive changes in parameters. Clustering of data noted both in BASDI and BASFI Score respectively at 4.3 and 5.7 cut-off respectively. All patients in both the sides of the cut-off showed variable improvement rate. It has also been observed during the analysis of data that over the period of 18 months of study those recruited with no or least complications and also in early stage of their disease showed higher improvement in BASFI Score as well as BASDI Scores. Rate of change of Functional Status and Disease activity also depend on various other factors may not be influenced by rehabilitation protocol at PMR Clinic and it also can critically influence the changes in final outcome at the end of study.

KEYWORDS

Axial Spondyloarthropathy, BASFI, BASDI, Rehabilitation

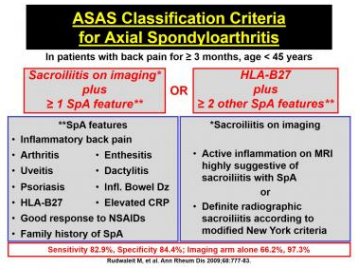
INTRODUCTION:

Spondyloarthropathies (SpA) is a heterogeneous group of chronic inter-related inflammatory arthropathies affecting mainly spine but also presents with symptoms at peripheral enthesis in the form of enthesopathy /Enthesitis with involvement of certain extra-articular sites like skin, Bowel, Eye (Uveitis) etc. Ankylosing Spondylitis (AS) is the most common form of Spondyloarthropathy presents with chronic, multisystem inflammatory disorder involving primarily the sacroiliac (SI) joints and the axial skeleton. Other groups of SpA includes Axial SpA including Ankylosing Spondylitis (AS), Peripheral SpA, Reactive Arthritis (ReA), Psoriatic Arthritis (PsA), Enteropathic Arthritis (associated with ulcerative colitis (UC), and Crohn disease) and Juvenile SpA (1).Non-radiographic axial Spondyloarthropathy is a term used to describe patients with predominantly axial features and includes patients with clinical features of AS but with normal plain radiographs of the sacroiliac joints and spin. This disorder probably represents an earlier phase or milder form of AS. Undifferentiated Spondyloarthropathy (USpA) is used to describe patients with predominantly peripheral features and may represent an early phase or incomplete form of AS or another spondyloarthropathy.

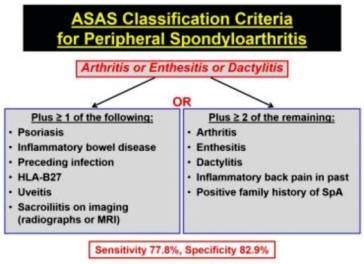


HLA-B27 Associated Diseases

SpA is seen in persons who are genetically predisposed to Major Histocompatibility Complex (MHC) - Class-I Molecule HLA-B 27. A direct relationship between AS and the HLA-B27 gene has been determined. [03, 04, 05, 06].



ASAS Classification Criteria for Axial SpA



ASAS Classification Criteria for Peripheral SpA

Clinically SpA presents with Inflammation of Spine and Sacro-Iliac (SI) Joint and involvement of the disco vertebral, apophyseal, costo-vertebral, and costo-transverse joints and the paravertebral ligaments along with Peripheral arthritis and Enthesitis *(Inflammation of Enthesis--the site of attachment of Tendons, Ligaments, Fascia or Joint Capsules to the Bones-Typical feature for SpA).* In early phase Subchondral granulation tissue erodes the joint and are replaced by Fibro cartilage followed by ossification mainly at enthesis *(results in*

Enthesitis) [07]. At spine it occurs at the junction of the vertebrae and the annulus fibrosus of the intervertebral discs initially. The annulus fibrosus of discs got ossified (syndesmophytes formation). Progressed to bamboo spine appearance. Pulmonary involvement due to inflammation of the costo-vertebral and costo-transverse joints, limits chest-wall range of motion (ROM). Asymptotic Pulmonary fibrosis found incidentally in radiographic examination. All these causes spinal pain and limitation of Movement with radiological evidence of structural changes at SI Joint and spine. Along with radiological progression severe mobility restriction for spine causes mild Enthesitis with adequate spinal mobility and good functional ability to reduced functional ability of spine is noted. As Axial SpA starts in early adulthood , it has high level of impact of disease over the life like stiffness, fatigue, limitation of social activities and reduced level of community participation (1).

Low back Pain, mainly at SI Joint, in 80 % patients of axial SpA including AS, Typical alternate buttock pain noted. Radiating of buttock pain is indication of sciatic nerve compression at root, Chest pain, sometimes 'pleuritic' in nature, noticed due to involvement of costovertebral and costo-transverse joint. Chest pain on coughing and sneezing is often noticed due to enthesitis of costosternal and manubrosternal joint. All these chest pathologies reduce chest expansions.

Restrictive lung disease with slowly progressive apical fibrosis occurs in patients with late-stage AS along with costovertebral and Costosternal involvement that limits chest expansion. Pulmonary ventilation maintained due to increased diaphragmatic contribution by compensating the limitation of ventilation due to chest wall rigidity Vital Capacity(VC) and Total Lung Capacity(TLC) moderately reduced due to restricted movement of chest wall but residual volume(RV) and functional residual capacity (FRC) are usually increased(2).

Functional impairment related to both Disease Activity and Disease Severity. Disease Activity can be assessed by Bath AS Disease Activity Index (BASDAI) (Table-01) and Disease severity can be assessed by using various approaches like functional Impairment, Limitation of Joint Range of Movement (RoM), and Hip Involvement, severity of radiological damage and Job Loss due to disease and so on ultimately ends of life. Functional assessment can be done by Bath AS Functional Index (BASFI) (Table-02) (01).

The age of onset of AS usually from 20-40 years of life but 10%-20% before16 years termed as juvenile-onset AS. Onset beyond 50 years is unusual and rare [08] Equal prevalence in men and women though men have severe radiographic changes in spine and hips than women [11] and clinical AS is more common in men than in women (M: F= 3:1) but undifferentiated SpA is more common in Female (F: M=3:1) [08, 09] [10]. With disease progression disability occurs due to spinal fusion, with thoracic kyphosis or erosion of peripheral joints (hips and shoulders). Spinal fusion is prone to spinal fractures followed by neurologic deficits. Highest level of functional loss occurs in first 10 years of AS [11]. 47% presents mobility with Problems and Disability is mainly related to the duration of the disease, peripheral arthritis, cervical spine involvement, younger age at onset of symptoms, and coexisting illnesses. Improvement of Disability occurs with appropriate rehabilitation protocol along with surgical correction of peripheral joint and cervical spine involvement if needed. Vocational counseling decrease the risk of employment disability by more than 60%.[14] Most patients able to work but up to 37% change occupations to less physically demanding jobs due disability. Emotional problems related to the disease are reported in 20% of patients. Depression common in women and it causes more pain and functional disability. USpA shows good-to-excellent prognosis.

An appropriate rehabilitation program reduces symptoms by increasing ROM and improvement of functional ability both in all forms of SpA including AS. Smoking cessation recommended because chest wall restriction and pulmonary complications in SpA. Study shows smoking was associated with higher disease activity and decreased function in AS. [15]. Treatment plan includes medications, rehabilitation exercise, and patient education and counseling Treatment measures include pharmacologic and Non Pharmacological Approach due to lack of single Disease Modifying Agent. In Pharmacological approach Tumor necrosis factor alpha (TNF-α) antagonists appear to have potential as disease-modifying agents. [16] In Non-Pharmacological Approach Rehabilitation including life style modification, therapeutic modalities, exercise protocol, functional training, RoM and Endurance training and surgical interventions including vertebral osteotomy, Fracture stabilization, and Joint replacement for deformity corrections are the mainstay under this approach. Rehabilitation exercises under appropriate need based protocol are important for maintaining function. [17, 18]. Water therapy and swimming are excellent activities for maintaining mobility and fitness. In addition, a meta-analysis concluded that aquatic physical therapy can statistically significantly reduce pain and disease activity in patients with AS. [19]. Postural training is also useful. Spinal extension and deep-breathing exercises help maintain spinal mobility, encourage erect posture, and promote chest expansion. Maintaining an erect posture during daily activities and sleeping on a firm mattress with a thin pillow also tend to reduce the tendency toward thoracic kyphosis.

With all these background objective of our study is to assess the effectiveness of an outpatient based rehabilitation programme in a group of patients with who are being treated with several pharmacological agents in various clinical setting, for improvement of functional ability along with control of disease activity. The response was calculated at the end of the structured outpatient day care rehabilitation protocol mostly at 12-week, 24 Weeks , 48 Weeks and 72 Weeks of follow-up visits after initiation of the rehabilitation program.

METHODS:

We designed a prospective study for 18 Months duration after getting the approval of its protocol from the organsational ethical committee from September 2017 February 2019 to. Patients were recruited from March 2017 to August 2017 who were treated conservatively different clinical discipline, were referred to PMR OPD for rehabilitation management. Review of diagnosis was made at PMR OPD with records, data as available corroborating with modified New York Criteria (20). Patients stable disease activity (BASDAI (3.2 to 3.5) and not requiring anti-TNF drugs with occasional NSAIDs were selected. Smokers, those with chest deformity, cardiac ailments or who are unable to tolerate rehabilitation protocols and/or having contraindication to therapeutic exercises were excluded from the study. All recruited patients were clearly explained about the process of the study and also informed consent was taken from them.

Disease Activity Assessment:

Patients considered active in disease in our study when, A) Pain is not controlled by NSAIDS; B) CRP is more than Three time of its reference and C) Any TWO of conditions is found on initial evaluation i) BASDAI is more than 4.1 or more ii) Global assessment 40 mm on VAS of 0 to 10 (10 being most severe) (iii) Pain VAS is 5 or more on 0 to 10 VAS Scale, iv) BASFI) value 40 mm

Functional Ability Assessment:

Patients were considered functionally compromised while BASFI is more than 5 and the 6-Min walk test for 10 meter is incapable by the patient with in stipulated time

Interventions

Patients after being recruited passes through regular exercise programme consisting of two daily sessions supervised by expert rehabilitation member including physiotherapist and occupational therapist as and when required. All patients were divided in groups including 6 patients and were observed by the physiatrists' investigators.

Every exercise session were divided into; ***(i)*** warm-up for 10 minutes then ***(ii)*** 30m minutes of strengthening exercises with maximal isometric pain free and dynamic contractions against gravity, then ***(iii)*** 20 minutes of stretching exercises with neuromotor facilitation. Then, ***(iv)*** a minimum 8-10 min of endurance exercises for a progressive duration depending on patient's functional capacity and disease severity finally ***(v)*** respiratory exercises for 10 min.

With all these programme when Patients tried to reach 60% of their predicted heart rate at maximal exercise for 5 days and then the protocol has been progressively increased to a HRmax of 80% of the predicted rate until the end of rehabilitation programme.

After 6 weeks of rehabilitation all patients were advised for daily home exercise programme, consisting thereof FIVE groups of exercises as

previously described during the week end periods.

Rehabilitation sessions were held in the hospital on FIVE days of the week. For the rest of the days, a home-exercise protocol was made available to each patient and was explained includes a detailed exercise prescription of aerobic exercise included walking, jogging etc., related to lower extremity, arm ergometry for upper extremity and a combination of both. For problem areas like hip, back, knee- strength training like resisted flexion, abduction, adduction or step up, leg push, hamstring curl etc. were advocated depending on the tolerability of the patients. Thoracolumbar and cervical mobility training were also imparted. To improve pulmonary function, breathing exercises, chest expansion etc., were prescribed.

Outcome assessment:

Outcome was assessed on BASFI, BASDAI and 6-Min walk capacity at the end of the rehabilitation at 12, 24, 36, 48 and finally 72 weeks after initiation of the rehabilitation protocol.

Every three months (±1 week), detailed assessment using the study tool was done. In addition to clinical examination, scoring for BASFI and BASDAI, lung function parameters were also assessed for every subject. BASFI and BASDAI were scored based on visual analogue scale on a scale of 0-10 with 0 indicating least no problem and 10 maximum problems. Pulmonary function was assessed using flow sensing spirometer. Pulse Oxymeter was used during assessment and also during therapeutic exercises protocol sessions to ensure safety of subjects with restrictive lung diseases. The lung function parameter values used during analysis were percentage of predicted values.

BASFI, BASDAI and 6-min walk test calculated and relative improvement and absolute improvement of 10 units in three or more of the following four domains, with no worsening in the fourth: inflammation (mean question 5 and 6 of the BASDAI), function (BASFI), patient perception of pain (patient pain VAS) and patient global assessment.

A case record form includes all relevant information on basic demographic profile, examination findings and scores of BASFI and BASDAI of all patients. This form also recorded and updated relevant information from the logbook, as is being maintained by the patient at home. In the log book all those information was made available for home exercise compliance as well as daily activity pattern. This helped ultimately to calculate MET (Metabolic Equivalent) score in subsequent period.

During every quarterly visit, till the end of this study each and every subjects were asked about their willingness to continue further in this study and any doubts or any difficulty they are facing to remain in the study were noted and recorded , if any were clarified during that time or later over phone, if necessary

RESULTS & ANALYSYS:

Out of 76 recruited patients 59 were male and 14 were female, with a men age of 47 .3 ± 9 with a disease duration of 8.3 ± 2.3 Years and 63(86%) were HLA B27 Positive. Out of all patients 23(31%) patients were on Anti TNF Inhibitors and 38(52%) were with csDMARDs like Methotrexate (MTX), Sulfasalazine (SSZ) and Hydroxychloroquine (HQ) and intermittent bridge course of Prednisolone (Oral) therapy. All were on NSAIDs (Mostly Etoricoxib or Indomethacine). Those responded with csDMARDs have presented with peripheral enthesitis also periarticular involvement in at Knee and Ankle. Pharmacological protocol of the referred department remains unaltered during the course of rehabilitation. Schedule follow up to the referred department were also continued during the period. 03 (0.04%) patient were discontinued the rehabilitation protocol for personal reason.

Changes in Outcome Measures:

After 24 weeks of rehabilitation 28 (38%) patient shows improvement of BASFI from 5.7 base line average to 4.3 and BASDAI of 6.2 baseline average to 4.9. At the end of 36 Weeks further improvement of BSAFI and BASDAI is noted. Here 43 (59%) patients show BASFI 4.1 and BASDAI 5.2. At the end of 48 Weeks of rehabilitation total 60 patients shows BASFI of 4.3 (Base line average 5.7) and BASDAI of 4.5 (Base line average 6.2) and at the end of 72 weeks of rehabilitation protocol we find BASFI of all 72 patient with average of 3.9 (Base Line average 5.7) and average BASDAI of 4.3 (Base line average of 6.2). Other than BASDAI & BASFI -6-minutes walk test also shows substantial improvement in length travelled from base line 25 meters to 35 meters in 48 Weeks and 45 weeks in 72 weeks. Changes in mean BASFI, BASDAI scores and Data of 6-minutes Walk test from one time point to the next were statistically significant as evident by results obtained from Wil coxon signed rank test. The changes of BASDAI and BASFI and 6-Miniutes Walks test was statistically significant with a p-value <0.0001. Most of the long term secondary outcome measures showed a statistically significant improvement at the end of rehabilitation programme and those were noted at 24 weeks and 48 weeks of follow-up. All anthropometric measures showed remarkable improvement with a statistically significant difference: tragus to wall distance improved at the end of rehabilitation which was noted at 24 and 48 weeks. Chest expansion also showed an improvement and this lasted throughout the four-point observations: in particular, at the end of rehabilitation a statistically significant difference was recorded, as well as for the modified Schober tests. Change of mean values of BASFI and BASDAI from T0 to T3 was analyzed using multiple linear regression model considering age of the subject, disease duration, vital capacity, FEV1/FVC, chest expansion, MET score etc. as predictor variable. In case of reduction of BASFI scores (Table 3) of individuals, disease duration was identified as the sole significant predictor. For changes in BASDAI (Table 4), age of subjects, baseline values of FEV1/FVC and BASDAI were identified as significant predictor. Overall, the two Bath indices showed good positive correlation (0.92), but correlation between percentage changes in the scores was less (0.46)

DISCUSSION:

Our study was done with patients of axial SpA in mild disease progression and moderate disease duration. In this stage scope of functional modification is high. Recruited patients were periodically assessed every 4 months on BASDAI, BASFI and 6 Minutes Walk ability Test over 18-month period. Selective Pulmonary function parameters also recorded to find out association with change in Bath indices. Baseline scores of Bath indices were similar to many other studies [21 to 25]. A study among 200 Ankylosing Spondylitis patients from Morocco [25] Reported BASDAI 4.08±2.23 and mean BASFI score 4.5. Cut off of BASDAI for Ankylosing Spondylitis compared to general population increased gradually from 0.9 in 18-29years, to 1.5 in 30-49years and 2.5 in persons aged more than 50years. Other study at UK [26] reported that the median age the cohort of 89 patients of Ankylosing Spondylitis was 50 years (inter-quartile range while median age of disease onset was 25 years and the median disease duration was 18 years. Our study shows a median age of 30 years with disease duration varying from 1 to 9 years. While comparing the UK based study [36] it has revealed that > 50 % (47/89) patients had BASDAI score of 4 or higher on the first assessment, of whom 45 (51%) continued to have 4 or higher on all subsequent assessments. In our study 10 out of 27 subjects (37%) had baseline BASDAI score of 4 or above. BASDAI scores correlated strongly with Bath Ankylosing Spondylitis Functional Index (BASFI) scores. Participants with persistently higher BASDAI scores showed higher scores for anxiety and depression compared to the other group of subjects with persistently lower BASDAI score. In the current study also some subjects were performing sub-optimally beyond a cut off value of 3.9 for BASDAI. Our study shows a mean BASDAI at baseline was **3.6+0.65** (Table 5) and BASFI was **4.0.3+0.55** and both data were comparable to other studies. Another study [27] conducted in China with two sets of patients receiving two different anti TNF-α agents. The baseline BASDAI scores were 4.92±1.75 and 4.31 ± 1.6 in two groups. After 6 weeks, BASDAI scores came down to 2.82 ± 1.65 and 0.96 ± 1.1. Our study clearly establishes the BASDAI of 3.60+0.65 at baseline and after 24 months, of treatment with Rehabilitation and NSAIDs, score was down to 3.46+0.69. Later the scores went down to 3.24+0.79. Similarly BASFI scores went down from 3.99±2.34 to 2.15±2.03 in one and from 2.40±2.26 to 0.67±1.11 in 6 weeks. In this study BASFI scores at baseline was 4.03+0.55 and later gradually reduced to 3.37+0.54. BASFI and BASDAI showed (27) significant positive correlation in that study with r=0.587 and 0.590 in two groups. In existing study also at baseline correlation between two scores was very high (r=0.9805). However, correlation between changes in two scores over time showed only a mild positive correlation with r= 0.2349. In the study mentioned above, similarly, correlation between changes of scores was quite low in one group [12] 0.345. Maximum decline for BASDAI in the current study was noted during the initial 6 months while that for BASFI was noted during 9th to 12th month. Overall, the two Bath indices showed good positive correlation (0.92), but correlation between percentage changes in the scores was not that

high (0.46). Changes in the scores over different time points were statistically significant. The pattern of change depended upon respective baseline values. Score of3.7 for BASDAI and 3.9 for BASFI split the cohort in two distinct groups where end-line scores vary. Pulmonary function test results and some other parameters were assessed during the study to identify predictors of change in Bath indices. In a study [28] conducted in 2011 at University of Oslo, Norway among 147 subjects, mean FEV1 was 89.8% and FEV1/FVC were 76.5%. The results were similar in another study from Uttar Pradesh, India [13].In the present study values of FEV1 at baseline was 72.7 and FEV1/FVC was 91.3%.

A study in UK (1996 to 2001) showed cases of sever Ankylosing Spondylitis have BASDAI scores remained mostly unchanged during follow up but the BASFI score became worsened (23). Our study shows a comfortable improvement in BASFI & BASDAI in early follow up and in later phase of follow up. A systematic review [29] on effect of TNF-α inhibitor used to estimate conditional change in BASDAI and BASFI scores among responder and non-responders**.** Another study in France noted that lung function parameters like vital capacity did not change much over time with therapy [30]. In active phase of disease chest expansion was correlated with vital capacity but neither was related to diseases activity. Another study from Taiwan [31] showed vital capacity, chest expansion to be correlated with BASFI. In this study also Bath indices were correlated with lung function values at baseline. European multi-country study [32] with 283 subjects shows overall change in BASDAI and BASFI scores after 4 weeks of NSAID therapy in terms of Minimum Clinically Important Improvement (MCII) &Patient Accepted Symptom State (PASS). Cut off for MCII were found to be 0.7 and 0.4 respectively for BASDAI and BASFI, while 4.1 & 3.8 for PASS. Baseline values and disease duration were important predictors for PASS and MCII scores. In our study change in BASFI was also dependent on disease duration and for BASDAI with age and baseline score were found to be important predictors

CONCLUSIONS:

We had studied our rehabilitation over moderate period of follow up with BASFI, BASDAI and 6-Min Walk Test for subjects in stages with moderate disease activity of Axial SpA, mostly of Ankylosing Spondylitis , which were medically managed by DMARDS and NSAID with a moderately higher level of functional inability/disability with corroborating level of disease activity but after addition of the OPD based rehabilitation programme there is significant improvement of functional ability as measured by BASFI and 6 –Min Walk Test and moderate reduction of disease activity and all these data showed statistically significant change from one time point to next. It has also been noted that the change in scores from baseline to the score during last follow up after 72 weeks as has been indicated that the BASFI change /improvement is associated with disease duration and rehabilitation programme continuation along with medical management on regular basis. This interpretation also applicable for changes in BASDAI during follows up with that of its baseline value, FEV1/FVC. Long term follow up may provide more information on pattern of change in indices and possible role of pulmonary functions on functional impairment or disease activity in the disease.

LIMITATIONS:

The study aimed to document changes in the Bath indices over time; however the study only focused on subjects in phase when structural damage may not be much in phase of the disease and naturally the result obtained cannot be generalized for severe forms of the disease. Secondly all patients were recruited in a smaller zone in relation to the area suffered from this disease in the continent, so the data may not be conclusive. Moreover indices like BASMI or BAS-G, if measured, would have provided more comprehensive insight into the problem.

TABLE-01: The BASDAI Score –

Please read each question you feel is the most appropriate to describe how severe your condition has been in the last week. Please put your feeling in SCORE BOX by choosing any digit from 0 to 10 as per the severity of your experience for each question. There is no wrong answer.

DESCRIPTION	SCORE
1. How would you describe the overall level of fatigue/tiredness you have experienced?: **0=*None,*** ***10=Very Severe***	
2. How would you describe the overall level of AS neck, back or hip pain you have had?.: **0=*None,*** ***10=Very Severe***	
3. How would you describe the overall level of pain/swelling in joints other than the neck, back or hips?: **0=*None,*** ***10=Very Severe***	
4. How would you describe the overall level of discomfort you have had from any tender areas to touch or pressure?: **0=*None,*** ***10=Very Severe***	
5. How would you describe the overall level of morning stiffness you have had from the time you wake up?: **0=*None,*** ***10=Very Severe***	
6. How long does your morning stiffness last from the time you wake up?: **0=*None,*** ***10=Very Severe***	
Calculating the BASDAI and its Interpretation: ***A****. Add scores for questions 1 – 4,* ***B****. Calculate the mean for questions 5 and 6.* ***C****. Add A and B and divide by 5. The higher the BASDAI score, the more severe the patient's disability due to their AS.*	
Adapted from Garrett et al. J Rheumatol 1994 21; 2286-91 2. Sieper, J et al. Ann Rheum Dis.2009,68:ii1–ii44	

TABLE-02: The BASFI Score –

Please read each question you feel is the most appropriate to describe how severe your condition has been in the last week. Please put your feeling in SCORE BOX by choosing any digit from 0 to 10 as per the severity of your experience for each question. There is no wrong answer.

DESCRIPTION OF QUESTIONs	SCORE (0 to 10)*
1. Putting on your socks or tights without help or aids (e.g., sock aid): **0=*None,*** ***10=Impossible***	
2. Bending forward from the waist to pick up a pen from the floor without an aid.: **0=*None,*** ***10=Impossible***	
3. Reaching up to a high shelf without help or aids (e.g., helping hand): **0=*None,*** ***10=Impossible***	
4. Getting up out of an armless dining room chair without using your hands or any other help: **0=*None,*** ***10=Impossible***	
5. Getting up off the floor without help from lying on your back: **0=*None,*** ***10=Impossible***	
6. Standing unsupported for 10 min without discomfort: **0=*None,*** ***10=Impossible***	
7. Climbing 12 to 15 steps without using a handrail or walking aid. One foot at each step: **0=*None,*** ***10=Impossible***	
8. Looking over your shoulder without turning your body: **0=*None,*** ***10=Impossible***	

9. Doing physically demanding activities (e.g., physiotherapy, exercises, gardening or sports): **0=*None*, *10=Impossible***	
10. Doing a full day's activities, whether it be at home or at work: **0=*None*, *10=Impossible***	
BASFI Score Calculation and result Interpretation: Add all scores from questions 1 -10 and divide by 10. The higher the BASFI score, the more severe the patient's limitation of function due to their AS.	
Adapted from Calin et al. J Rheumatol. 1994 Dec;21(12):2281-5.	

Table- 3: Multiple linear regression model for change in BASFI (T0-T3).

Parameters	B	Std. Error	Beta	t-statistic	p-value
(Constant)	1.645	1.814		0.907	0.378
Vital Capacity	0.006	0.032	0.28	0.188	0.853
Total Lung Capacity	-0.009	0.025	-0.402	-0.356	0.726
FEV1	-0.005	0.015	-0.188	-0.312	0.759
FEV1/FVC	0.024	0.021	0.311	1.141	0.271
Chest Expansion	-0.022	0.062	-0.07	-0.355	0.728
SaO2	-0.018	0.022	-0.185	-0.819	0.425
MET	-0.013	0.028	-0.085	-0.448	0.66
BASFI-baseline	-0.109	0.084	-0.361	-1.293	0.214
Age	-0.002	0.007	-0.082	-0.3	0.768
Disease Duration	-0.057	0.019	-0.855	-3.026	.008*
Model	**R**	**R Square**	**Adjusted R Square**	**Std. Error (Estimate)**	
1	0.82	0.672	0.467	0.12154	
Dependent: change in BASFI (T0-T3), Predictors: (Constant), disease duration, SaO2, TLC, Chest Expansion, MET, FVC, Age, baseline BASFI, FEV1/FVC, VC					

Table-4: Multiple linear regression model for change in BASDAI (T0-T3) –

Parameters	B	Std. Error	Beta	t-statistic	p-value
(Constant)	8	2.2			0.002
FEV1/FVC	-0	0	-1		.006*
Age	-0	0	-1		.013*
Disease Duration	0	0	1		0.061
BASDAI-baseline	-0	0.1	-0		.018*
Model Summary					
Model	**R**	**R Square**	**Adjusted R Square**		**Std. Error of the Estimate**
1	.682a	0.47	0.367		0.19609
Dependent: change in BASDAI; Predictors: (Constant), baseline BASDAI, Age, FEV1/FVC, disease duration					

Table 5: Summary values of lung function parameters obtained at baseline for the subjects –

Parameters	Average	Range	Reference range31
Vital Capacity (VC)	70.07±7.71	56-82	80-120
Total Lung Capacity (TLC)	71.44±7.54	58-84	80-120
FEV1	72.77±6.68	64-86	
FEV1/FVC	91.30±2.16	88-96	Within 5% of predicted
Chest Expansion	2.79±0.52	2.1-3.8	
SaO2	93.96±1.69	91-97	
MET	5.44+1.12	7-Mar	
6MWT	925.3704	850-1060	
BASDAI	3.60±0.65	2.7-4.45	
BASFI	4.03±0.55	3.2-4.9	

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