

# Functional Improvement in Ankylosing Spondylitis from Pharmacological and Non-Pharmacological Management – an Observational Study

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## ABSTRACT

**Background:** To evaluate the efficacy of pharmacological and non-pharmacological management in Functional improvement in patients of Ankylosing Spondylitis. **Methods:** Thirty-two (32) Patients of Ankylosing spondylitis diagnosed by international society classification criteria were selected between February 2016 and December 2018 in this prospective study after institutional ethical clearance. These patients divided into two groups randomly and group 1 was given therapeutic exercises only and group 2 was given therapeutic exercises and sulfasalazine. Both were evaluated for chest expansion, BASMI, BASFI, BASDAI, BAS-GLOB at baseline and after 3 months. **Results:** Ankylosing spondylitis usually affects young adults in between 20-30 years. Male predominance over female is seen. ratio being 7:1. Regular exercise with or without sulphalazine improved the functional parameters but there was no statistically significant improvement in clinical and functional variables between the pharmacological and non –pharmacological group. So sulfasalazine did not show any added benefit in axial Ankylosing Spondylitis. **Conclusion:** From our study it can be concluded that Ankylosing spondylitis usually affects young adults in between 20-30 years. Male predominance over female is seen. ratio being 7:1. Regular exercise and NSAID improved the functional parameters but there was no statistically significant improvement in clinical and functional variables between the pharmacological and non –pharmacological group. So patients need to be counselled about regular exercise, posture care and life style modification in cases of axial spondylitis.

**Keywords:** Ankylosing Spondylitis, Pharmacological, Community Medicine.

## INTRODUCTION

Ankylosing Spondylitis is one of the prototypes of spondyloarthritis. Onset of spondyloarthritis generally occurs between second to fourth decades, which is the most important period for socioeconomic productivity. As of date, there is no definitive pharmacological management offering permanent cure for Ax-spA (Of those pharmacological therapies which are used for control Ax-spA,<sup>[1]</sup> Disease Modifying Anti Rheumatic Drugs (DMARDs) were not proven to be effective, whereas biologics are costly, having multiple adverse effects on different organs along with the increase in susceptibility to different infections, less acceptable to the patient population of developing countries like India.). Hence, restoration of physical function, disability limitation, and effective pain management is the felt need in this population for improving the quality of life and sustaining socioeconomic productivity.

There have been only a few studies that have studied the role of DMRDs in axial Spondyloarthritis. In reality, most of the studies were of different duration of

intervention, lacks standardized exercise program and multidisciplinary institutional approach. Hence, this study was planned to assess the improvement in clinical and functional parameters after a 6-months of treatment of pharmacological and non-pharmacological methods.

## MATERIALS AND METHODS

This prospective clinical trial was approved after Institutional Ethical Committee clearance and individual informed consent (both written and verbal). Patients were enrolled between Feb 2016 and Dec 2018. The study was conducted at outpatient department of Physical Medicine and Rehabilitation of IPGME&R SSKM Hospital, Kolkata. Thirty two patients diagnosed as Ax-spA by assessment of spondyloarthritis international society classification criteria.<sup>[2]</sup> within the age group 18 years to 45 years, were included in the study, the exclusion criteria was active non-inflammatory spinal disease, Hip and Knee deformities, recent biologic treatment, postsurgical history on axial skeleton or peripheral joints, systemic diseases like hypertension, diabetes, psychiatric illness, heart diseases, equilibrium disturbances, or pregnancy.

The patients were counselled about the nature and progression of the disease.

The demographic and clinical details of all the patients were recorded –age, gender, economic status, Occupation, Duration of illness, General health,

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Onset, Age of onset of symptoms, Site of onset, history of associated symptoms, presenting symptom, Constitutional symptoms. Baseline ESR, CRP was done. Also baseline chest expansion, BASMI, BASFI, BASDAI, BAS-GLOB was done. The patients were then divided randomly into two groups. Group 1 received indomethacin non-pharmacological treatment comprising of posture care and exercise while the second group was given sulfasalazine tablet, 1g twice daily along with exercises and indomethacin. Follow up observation was done after 3 months.

## RESULTS

Thirty-two (32) patients were recruited for the study over a period of 2 years. No patient was lost to follow up. (16) 50% of the patients were 21 to 30 years. The youngest and the oldest patients were aged 18 and 53 years respectively. Out of the 32 patients with AS 28 were males and 4 were females. Male : female was 7 : 1. Economic status: around 43.% (14) patients were from middle income group while 37.5% (12) were having income of less than Rs 3000 per month. Occupation: A mixed occupation was seen but

maximum patients (31.25% patients were manual laborers. In our study we had more patients 59.37% patients with recent onset illness with Duration of illness less than 5 years. In this present study most of the patients had insidious onset. 93.75% (30 patients) 8.75% of patients were young adults with their Age of onset of clinical features between 20 to 30 years. On first visit 14 had ESR in the range of 31-60 mm, 12 had ESR more than 60 mm.

**Table 1: ESR of Visit 1**

S. No	ESR in mm	No. of Cases	Percentage
1	upto30	6	18.75%
2	Between 31-60	14	43.75%
3	More than 60	12	37.50%
Total		32	100%

Comparisons of numerical variables between group 1&2 by Mann-Whitney u Test, it was found that in visit 2, p value in respect to ESR has become statistically significant, the value being 0.022. Chest expansion measurement done in first visit it was observed most of the patient had chest expansion 2.5 cm or less (62.5%).

**Table 2: Change in numerical variables from visit 1 to visit 2 in GROUP 1 – Wilcoxon’s matched pairs signed rank test**

	Valid N	T	Z	P-level
1) Chest expansion	16	12.00000	0.840168	0.400815
2) ESR	16	44.00000	0.104828	0.916512
3) BASMI	16	2.50000	0.912871	0.361311
4) BASFI	16	31.50000	0.588348	0.556299
5)BASDAI	16	1.00000	2.701130	0.069111
6) BAS-GLOB	16	12.50000	1.528942	0.126280

**Table 3: Change in numerical variables from visit 1 to visit 2 in GROUP 2 – wilcoxon’s matched pairs signed rank test**

	Valid N	T	Z	P-level
1) Chest expansion	16	6.00000	1.352247	0.176297
2) ESR	16	15.00000	2.131513	0.033048
3) BASMI	16	2.50000	0.912871	0.361311
4) BASFI	16	22.00000	0.978019	0.328066
5)BASDAI	16	7.00000	1.836282	0.066317
6) BAS-GLOB	16	16.00000	1.172189	0.241122

Above table shows that ESR has statistical significant p value (0.033048). It indicates that sulfasalazine has added advantage in reducing ESR in AS patients but the chest expansion, BASMI, BASFI BASDAI, BAS-GLOB

## DISCUSSION

Age of onset in Ankylosing spondylitis was found most commonly in the 15-24 years. 10% develop symptoms before puberty.<sup>[3,4]</sup> AS affects young adult men.<sup>[5]</sup> In my study 16 patients i.e. 50% were in the 21-30 years age group. Also 24 patients had their age of onset in 20-30 decade. In rest of the patients (8 in no) age of onset was in 31-40 decade.

Sex ratio varies in survey from 9:1 to 4:1.<sup>[6]</sup> In this study the male to female ratio was 7:1. As far as occupation is concerned 31.25% was from labour class and 25% were students. In most cases no

change of general health is noticed.<sup>[7]</sup> In my study also majority of patients 56.25% (18 in no) were of moderate health by insidious onset of AS is observed in approximately 80% patients.<sup>[8]</sup> Here 93.75% (30 in no) patient’s mode of onset was insidious. Commonest first symptom as well as commonest symptom in AS is low backache.<sup>[9]</sup> In this study 87.5% (28 in no) patient’s site of disease onset was in the axial skeleton and 24 of them presented with low backpain without radiation as the initial symptom.

The patients were followed up after 6 months after prescribing with exercise, NSAID, and sulfasalazine (used in some patients). Clinical and functional improvement was seen though all of them may not have shown statistical significant p value. Though there was mild improvement in chest expansion in some patients but it was not significant. In general patients had come with raised ESR, characteristic of

ankylosing spondylitis. On first visit 14 had ESR in the range of 31-60 mm, 12 had ESR more than 60 mm.

On follow up it is being seen that there is statistically improvement in this parameter especially in the patients getting sulfasalazine (Group 2 in this study). Comparison of value of ESR between group 1 and 2 by Mann-Whitney U test shows significant P value of .022. Change in value from visit 1 to visit 2 in group 2 receiving sulfasalazine by Wilcoxon's matched pairs signed rank test shows significant P value of .033.

So sulfasalazine has significant role in reduction of ESR. There are a no of studies including one by Clegg in 1996,<sup>[10]</sup> showing reduction of ESR with sulfasalazine in ankylosing spondylitis patients. CRP was positive in 20 patients that came down to 16 on follow up. An improvement which is not statistically significant. BASMI on first visit, 30 had score upto 5 and 2 had score more than 5. On follow up these statistics remained unchanged. BASFI on first visit, 18 had score upto 5 and 14 more than 5. On follow up 19 patients had score upto 5. Though this improvement in functional index is not statistically significant. BASDAI on first visit, 23 had score upto 5 and 9 had score more than 5. On follow up these statistics remained unchanged. BASG on first visit, 15 had score upto 5 and 17 more than 5. On follow up 17 patients had score upto 5. Though this improvement in global score is not statistically significant.

## CONCLUSION

From our study it can be concluded that Ankylosing spondylitis usually affects young adults in between 20-30 years. Male predominance over female is seen. ratio being 7:1. Regular exercise and NSAID improved the functional parameters but there was no statistically significant improvement in clinical and functional variables between the pharmacological and non-pharmacological group. So patients need to be counselled about regular exercise, posture care and life style modification in cases of axial spondylitis.

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