

Case Series

Pain management in ankylosing spondylitis and their response to biological - Case series

Lokesh SB¹, Latha V^{2*}

¹Dept. of Anaesthesiology, ESICMC PGIMS and Model Hospital, Rajajinagar, Bengaluru, Karnataka, India

²Dept. of General Medicine, ESICMC PGIMS and Model Hospital, Rajajinagar, Bengaluru, Karnataka, India

Abstract

Ankylosing Spondylitis (AS) is a chronic inflammatory disease affecting the axial skeleton, with variable involvement of peripheral joints and extraarticular structures. Ankylosing spondylitis one of the types of seronegative rheumatoid arthritis and is a common rheumatological condition. The prevalence of AS closely parallels the frequency of *HLA-B27*. The average global prevalence rates are estimated as 238 per 100,000 in Europe, 319 per 100,000 in North America, and 167 per 100,000 in Asia. Current options of treatment includes NSAIDs and BIOLOGICALS for both pain management and for halting the disease progression. Here we are presenting 6 cases with various symptoms and signs of ankylosing spondylitis and we also like to discuss the pain management and patients response to monoclonal antibodies.

Keywords: Ankylosing spondylitis (AS), Seronegative rheumatoid arthritis, Biologicals.

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1. Introduction

Spondyloarthritis (SpA) refers to a group of overlapping disorders that share clinical features, genetic associations, and pathogenic mechanisms. The classic designations include ankylosing spondylitis (AS), reactive arthritis (ReA), psoriatic arthritis (PsA), arthritis associated with inflammatory bowel disease (IBD), juvenile spondyloarthritis (JSpA), and undifferentiated SpA.¹

Ankylosing Spondylitis (AS) is a chronic inflammatory disease of insidious onset. The primary pathologic site is the entheses, or site of insertion of tendons or ligament cap.

AS is classified as axial spondyloarthritis and nonradiographic axial spondyloarthritis (nr-axSpA), which refers to individuals meeting clinical criteria for axSpA without radiological evidence of sacroiliitis.¹

The prevalence of AS closely parallels the frequency of *HLA-B27*.^{2,3} The average global prevalence rates are estimated as 238 per 100,000 in Europe, 319 per 100,000 in

North America, and 167 per 100,000 in Asia.⁴ From study conducted by Joshi VL et al, and Chopra et al the prevalence of AS in India varies 7 to 9.8 per 10 000 population.⁸

Diagnostic criteria used are Rome, 1961, Modified New York, 1984, ASAS Classification criteria (Assessment of Spondylo Arthritis International Society, Table-1). Pain management is an integral part in management of Ankylosing Spondylitis (AS). Here we are presenting case series, where we discuss the pain management and monoclonal antibodies given to patients and their response.

2. Case Description

2.1. Case 1

A 23 yr. old male presented with history of pain in right knee and ankle joint pain since 3 to 5 months, which was insidious in onset gradually progressive, initially patient was able to walk with pain, however over from past 1 month patient needs assistants to walk because of pain and swelling in knee and ankle joint which started simultaneously in both joints.

*Corresponding author: Latha V
Email: ambujalatha@gmail.com

Aggravating factor was movements; patients particularly complain of pain in right heel over the insertion of Achilles tendon, patient had history of pain and mild swelling over left knee and ankle joint since 1 month. Patient had history of low back ache since 5 to 6 months, which was insidious in onset gradually progressive, which is more over right gluteal region. Patients said pain is gradually increasing and aggravating factor was rest, relieving factor is medication. There is on and off history fever since 3 months, relieves on medication, not associated with chills and rigors. Patients vitals, clinical examination details, blood investigation including MRI sacroiliac joint is given in **Table 2** and 3. Patient was initially treated with NSAID (ibuprofen with paracetamol, titrated to maximum dose) according to 2016 Update of the ASAS-EULAR Recommendations for the Management of axSpA. Initially up to 1.6yrs patient showed both clinical and radiological improvement, later patients had high disease activity (BASDAI score-9) in spite maximum dose of NSAIDS and intraarticular glucocorticosteroids, hence TNFi therapy was started i.e adalimumab 40mg s/c every 4 weeks. Patient responded well. His BASDAI scores came down and inflammatory markers also came down.

2.2. Case 2

A 32 year female presented with complaints of pain in right lower back and B/L elbow since 4 months. Back ache increase in morning and reduces as the day goes by. Patient also complained of fever on and off episodes since 2 weeks, no history suggestive of foci of infection. No history of redness or pain in eye, no history of diarrhea. On examination vitals stable, tenderness in right sacroiliac joint present, b/l elbow joint, wrist joint and hand small joint pain on passive movements present. Patient was admitted and evaluated. X-ray spine was done which revealed erosion in lumbar vertebrae, paraspinal muscle spasm with loss of lumbar lordosis.

Patients' blood investigation and other clinical details and MRI findings are given in table no 2 and 3. Patient was started on NSAIDS (ibuprofen with paracetamol), sulfasalazine was also started because of peripheral joint involvement. However after 6 month of NSAIDS patient started having his symptoms recur, NSAIDS titrated to maximum dose and intraarticular steroids were also considered, later patient improved for 12 months and later patient started having high BASAID SCORE(>8), due to which injection adalimumab 40 mg subcutaneously once a month was started. Patient gradually improved after 2nd dose of biologics, later completely pain free after 6 months and was continued with adalimumab.

2.3. Case 3

A 42 year female presented with complaints of back ache and stiffness since 1 month which was gradually progressive

associated with stiffening of the spine and hip. Patient also had similar episodes two months back. No history of redness of the joint or skin rashes. No history of diabetes, hypertension, no history of redness or pain in eye, no history of diarrhea. Examination revealed kyphosis, stooping forward position of the neck and flexion deformity of both the hip joints. Patients' blood investigation is given in **Table 1** and **2**. MRI Lumbosacral Spine with Whole Spine Screening showed cervical, thoracic, and lumbar spondylitis changes with multilevel degenerative disc changes, articular margin irregularities with STIR hyperintensity suggestive of edema noted in both sacroiliac joint, both iliac and sacral bones, features suggestive of bilateral sacroilitis. Patient was started on NSAIDS initially and reached maximum dose, patient did very well for 1year with maximum dose of NSAIDS, later he started having high BASAID score. Patient did very well 1 year with both NASIADS. Later patients started having increased in pain and hence monoclonal antibodies i.e Adalimumab 40 mg subcutaneously once a month was started with opiod like drugs (oxycodone with acetaminophene for 1 month) was started .patient gradually improved with inflammatory markers negative at the end of 3months.

2.4. Case 4

A 29 year old male patient presented with complaints of low back ache since 3 years which was associated with pain in the neck and shoulder region. Pain was dull, non-radiating, gradually progressive in intensity and duration, initially patient was able to walk but later patient was unable to get up from bed and had difficulty in doing routine activity because of pain. No other comorbidities. MRI spine with hip and Blood investigations mentioned in **Table 2** and **3**.

Patient was started on NSAIDS initially and reached maximum dose, patient did very well for 2yrs with maximum dose of NSAIDS. Patient did very well 2 years with both nasiads for 2yrs. Later patients started having increased in pain with high BASAID score and hence monoclonal antibodies i.e Golimumab 50 mg every 4 week. Patient started showing improvement to biologicals 1month, later patients was pain free and able to carry out all his work.

2.5. Case 5-6

A 44 and 38 year old male presented with history of left sided low back ache since 6 months which was insidious in onset gradually progressive, more in night and no other organ system manifestation. Patient's investigation details is in **Table 2** and **3** patients was initially started on NSAID and patient continue to responded well. For all patients Wong-Baker FACES pain rating scale was used for both initial assessment and for follow up. All patients were educated about axSpA and encouraged to exercise on a regular basis, physical therapy and stop Smoking.

Table 1: ASAS classification criteria for axial spondyloarthritis in patients with back pain 3 months or more and age at onset younger than 45 Years.

Sacroiliitis on imaging + ≥1 SpA feature	HLA-B27 positive + ≥2 other SpA features
Sacroiliitis on imaging <ul style="list-style-type: none"> Active (acute) inflammation on MRI highly suggestive of SpA-associated sacroiliitis (Bone marrow edema and/or osteitis on STIR or gadolinium-enhanced T1 image) And/or <ul style="list-style-type: none"> Definite radiographic sacroiliitis according to modified New York criteria. 	SpA features: <ul style="list-style-type: none"> Inflammatory back pain Arthritis Enthesitis (heel) Anterior Uveitis Dactylitis Psoriasis Crohn's disease/UC Good response to NSAIDs Family history of SpA HLA-B27 Elevated CRP

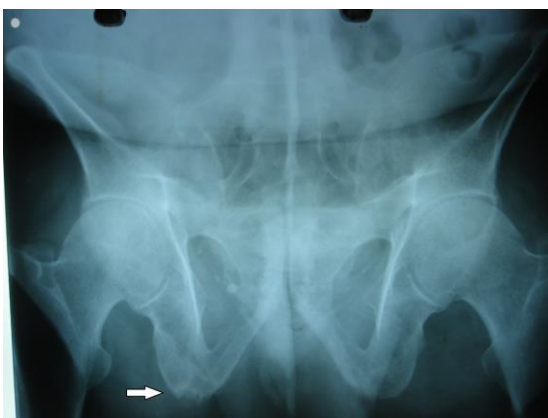
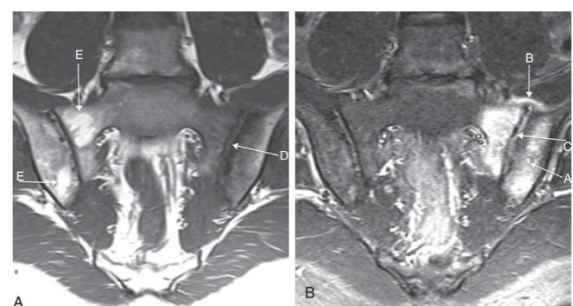
Table 2: Investigation

S.No	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Haemoglobin(gm/dl)	10.7	11.2	13.4	12.1	11.6	10.6
Total count(c/mm ³)	7500	7200	6800	5600	8400	6700
Platlet count(lakhs/mm ³)	1.4	2.1	2.7	3.1	3.4	1.8
GRBS (mg/dl)	120	111	121	104	108	140
Blood urea (mg/dl)	22	18	17	16	24	15
Serum creatinine (mg/dl)	0.6	09	1.2	1.06	1.0	0.5
Sodium (mmol/l)	136	139	138	141	140	137
Potassium (mmol/l)	3.5	4.4	4.2	4.5	4.8	4.5
Chloride (mmol/l)	103	101	104	103	100	99
ESR	80	96	110	120	74	89
CRP	Positive	Positive	Positive	Positive	Positive	Positive
HIV/Hbsag/HCV	Negative	Negative	Negative	Negative	Negative	Negative
LFT	Normal	Normal	Normal	Normal	Normal	Normal
HLA-B27	Positive	Positive	Positive	Positive	Positive	Positive
X-ray lumbar spine	Degenerative changes in lumbosacral region	Straightening of spine with	normal	normal	normal	Degenerative changes in lumbosacral region
X-ray sacroiliac joint	Early erosion changes in right subchondral area of sacroiliac joint.	Early erosion changes in subchondral area in b/l sacroiliac joint.	Suggestive of sacroiliitis	Early erosion changes in subchondral area	ankylosing of sacroiliac joint and illdefined erosion.	Early erosion changes in subchondral area
X-ray chest	Normal	Normal	Normal	Normal	Normal	Normal
MRI sacroiliac joint	focal area of bone marrow edema in an anterior slice of the left sacrum(T1-weighted sequence) There are no other structural abnormalities to suggest a diagnosis of	MRI scan depicting bone marrow edema in the left iliac bone in early axial spondyloarthritis. T1-weighted sequence and left iliac erosion with loss of cortical bone, loss of adjacent marrow matrix. Short tau	Cervical, thoracic, and lumbar spondylitis changes with multilevel degenerative disc changes, articular margin irregularities with STIR hyperintensity	Bone marrow edema in left sacrum. There are no other structural abnormalities to suggest a diagnosis of axial spondyloarthritis	T1-weighted MRI of the sacrum from the patient indicates cortical erosion of the right SI joint, C. Short tau	focal area of bone marrow edema in an anterior slice of the left sacrum(T1-weighted sequence) suggestive of spondyloarthritis

	axial spondyloarthritis	inversion recovery sequence- bright signal in two locations indicating bone marrow edema in the left sacral and iliac bone on a single semicoronal slice through the sacroiliac joint.	suggestive of edema noted in both sacroiliac joint, both iliac and sacral bones, features suggestive of bilateral sacroilitis.		inversion recovery (STIR) sequence MRI from the same patient shows bone marrow edema on both sides of the SI joint	
RA Factor	Negative	Negative	Negative	Negative	Negative	Negative
ANA level	Negative	Negative	Negative	Negative	Negative	Negative
ANA profile	Negative	Negative	Negative	Negative	Negative	Negative
Treatment given	Adalimumab	Adalimumab	Golimumab	Adalimumab	NSAIDS	NSAIDS

Table 3: Extrarticular manifestation and HLA-B27

S.No.	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
1. Schober's test	Positive	Positive	Positive	Positive	Positive	Positive
2. Lateral bending measure	Positive	Positive	Positive	Positive	Positive	Positive
3. Chest expansion	Normal	Normal	Normal	Normal	Normal	Normal
4. Inflammatory back pain	Present	Present	Present	Present	Present	Present
5. Arthritis	Present	Present	Present	Present	Present	Present
6. Enthesitis (heel)	No	No	No	Present	No	Present
7. Uveitis	No	No	No	No	No	No
8. Dactylitis	No	No	No	No	No	No
9. Psoriasis	No	No	No	No	No	No
10. Crohn's disease/uc	No	No	No	No	No	No
11. Family history of spa	No	No	No	No	No	No
12. Basdai before starting monoclonals	8	9	9	8.5	6	8
13. Basdai after starting monoclonals	0	0	0	0	-	-
14. Osteoporosis	Yes	Yes	Yes	Yes	Yes	Yes
15. Fatigue	Yes	Yes	Yes	Yes	Yes	Yes
16. Weight loss,	Yes	Yes	Yes	Yes	Yes	Yes
17. Low- grade fever	Yes	Yes	Yes	Yes	Yes	Yes

**Figure 1:** X-ray pelvis frontal view of Case no 5 showing ankylosing of sacroiliac joint and illdefined erosion.**Figure 2:** Mri sac-iliac joint of patient no 1-T1-weighted; A: and short-tau inversion recovery sequence MRI (B) of a 23-year-old male with inflammatory back pain and equivocal pelvic radiograph demonstrating the following features: A: Bone marrow edema in left iliac and sacral bones; B: Capsular inflammation; C: Joint space inflammation; D: Siffuse erosion of left iliac bone with widening of joint space; E: Fat lesion.

3. Discussion

In AS The most common presenting symptom is inflammatory low back pain i.e "Inflammatory back pain" typically exhibits at least four of the following five features:- Age of onset <40 years, Insidious onset, Improvement with exercise, No improvement with rest Pain at night (with improvement upon arising).^{2,8} In our series all 6 patients had predominant presenting complaint as low back ache.

Estimates of the proportion of adults with chronic back pain having inflammatory back pain (IBP) vary between 2.3% and almost 25%. At 10 years, the probability of having spondyloarthritis for patients with IBP was 30%, while the resolution of IBP occurred in 43%.^{9,10} And thus according to current data the IBP in clinical practice, is often may not be well recognized.¹⁸ Hence it is important to recognize the inflammatory back pain, so that ankylosing spondylitis is detected early.

All of our patients were diagnosed based on ASAS criteria. Of ASAS criteria has sensitivity 83% and specificity 84%.¹ In our series all 5 patients had HLA-B27 positive. HLA-B27 is found in 85% to 95% of cases of primary AS.⁴

The pathological process in AS process usually starts at the sacroiliac joint, Pathogenesis of AS is briefly described in **Figure 3** and **4**. The following pathogenic process explains why there is early and best response of pain by NSAIDS and also explains the role of TNFi.⁸

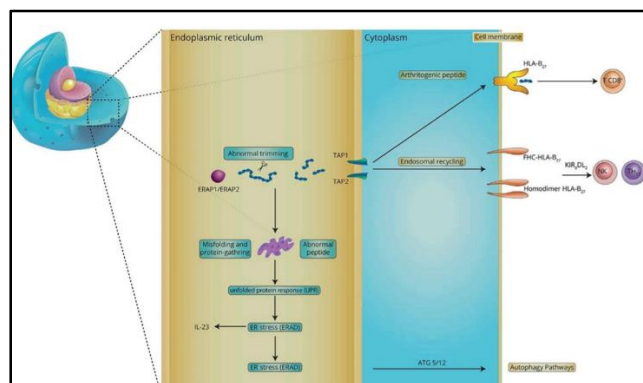


Figure 3: Demonstration of the possible role of HLA-B27 and ERAP1/2 in AS pathogenesis. HLA-B27 can present arthritogenic peptides to CD8+

T lymphocytes, which trigger AS initiation. Peptides enter the ER and are further trimmed by ERAP1 and ERAP2. Unusual peptides will be produced because of incorrect ERAP1 or ERAP2 trimming, leading to HLA-B27 free heavy chains (FHCs) and homodimers through endosomal recycling from the cell membrane and then to NK cell and Th17 cell activation by KIRs, particularly KIR3DL2. Abnormal peptide-HLA-B27 complexes gather in the ER, triggering UPR, ER stress, ER-associated protein degradation (ERAD) and autophagy.

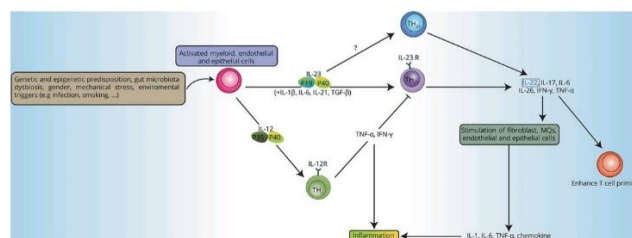


Figure 4: IL-23/17 pathway in AS pathogenesis. The interplay of genetic and epigenetic influences, particularly Th17 and Th22 cells, with a few kinds of stress, such as mechanical stress, gut microbiota stress, and environmental triggers, gives rise to the production of pro-inflammatory molecules, including IL-17, IL-22, TNF-α, and IL-23.

Extra musculoskeletal Manifestations are Constitutional symptoms such as fatigue, weight loss, and low- grade fever, acute anterior uveitis (AAU) or iridocyclitis (is the most common extra-articular manifestation of AS occurring in 25% to 30% of patients). Manifestations of cardiac involvement include ascending aortitis, aortic valve incompetence, conduction abnormalities, cardiomegaly, and pericarditis. Lung involvement is a rare and late manifestation of AS. It is characterized by slowly progressive fibrosis of the upper lobes of the lungs, appearing, on average, 2 decades after the onset of AS. Neurologic complications- vertebral fracture, instability, compression, or inflammation. GIT- inflammatory bowel disease (IBD). Renal complications- Immunoglobulin IgA nephropathy. Osteoporosis Decreased bone mineral density (BMD) can be seen in early stages of AS. It is reported in more than 50% of patients with less than 10 years disease duration. The overall prevalence of osteoporosis is about 15%.¹⁰ However, these extra-articular manifestations differ between East Asian and Caucasian populations. In a study involving 988 patients with ankylosing spondylitis in east Asia, only 0.4% developed inflammatory bowel disease.¹ However, in some analyses performed in Western countries, ~5% 10% of patients with AS present with inflammatory bowel disease.² In our series, most common extra musculoskeletal involvement is fatigue, weight loss, and low- grade fever. In the study conducted by Rohit Agarwal et al¹¹ most common extra axial involvement was anterior uveitis.

In study conducted by Rohit Agarwal et al¹³ conducted in India out of 70 patients male to female ratio was 5:1 and Mean age of diagnosis was 23.6(men) and 32.5(women) years. In our series we had 4 male and 2 female patients. In our study mean age of men was 26.3 in men and 34.5 years. In study conducted by Rohit Agarwal et al¹¹ extremities involvement with asymmetrical pattern was 65.7%. In our study it was 90%.

According to 2016 Update of the ASAS-EULAR Recommendations for the Management of axSpA, Patients suffering from pain and stiffness should use an NSAID as first-line drug treatment up to the maximum dose. NSAIDS not only acts analgesics they also helps in reduces the

inflammatory markers. In our patients all were given NSAIDS as the 1st line of treatment, all patients responded well for a considerable amount of time, our patients also responded well to intraarticular glucocorticosteroids and opiod like medication and hence reduced the burden of price of biological.^{12,13} In the study conducted by Marlies J. G. Carbo et al¹⁴ 412 patients of AS, showed that there was a good response to NSAIDS and showed that use of NSAIDS will reduce the burden of cost of biological.

TNFi are recommended in AS/axSpA with a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥ 4 (at least moderate disease activity) for AS specifically.¹⁴ In our series all patients who were started on biological had BASDAI score of >5 and all 4 of them showed excellent response to treatment. In the study conducted by Ulf Lindström et al¹⁵ two thousand five hundred ninety patients started a first TNFi 2006–2015 all the patients responded well and about 30 % of patients were completely anti-rheumatic free for more than 5 yrs.

4. Conclusion

AS is not an uncommon disease in India. It is important to identify these patients early with typical inflammatory low back ache. Early detection of clinical features with prompt MRI sacroiliac joint helps in early treatment initiation. Our case series showed Non-steroidal anti-inflammatory drugs (NSAIDs) are as the cornerstone of conventional treatment for AS. Pain management by the expertise are the best, prompt and effective increase in dose helps patient to early alleviation of pain and reduces the cost burden of biological. However when there is need for biological clinicians should not hesitate to start it. In our series, patients not only showed a good response to NSAIDS but also an excellent response to monoclonal antibodies. Hence we recommend clinicians to use NSAIDS as 1st line and not to hesitate to start biological when required.

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None.

6. Conflict of Interest

None.

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