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Original Article

Gender-Based Disparities and Delayed Diagnosis in Egyptian Patients with Axial Spondyloarthritis: A Cross-sectional Study

Ebtesam Fayez, Essam Abulfadl, Ahmed Elsaman, Toqa Elbakry, Asmaa Khalifa

*Department of Rheumatology, Physical Medicine and Rehabilitation, Faculty of Medicine, Sohag University, Egypt

Abstract:

Background: Axial Spondyloarthritis (axSpA), including Ankylosing Spondylitis and non-radiographic axSpA, presents diagnostic challenges, with significant delays in diagnosis and unmet treatment needs, particularly in Egypt. This study aims to address these gaps, focusing on the Egyptian context and highlighting the disparity in disease burden and management between genders.

Aim: To enhance awareness and understanding of axSpA in Egypt, with a focus on unmet needs, especially in delayed diagnosis and gender-specific disparities in disease management.

Methods: An observational, cross-sectional study was conducted at Sohag University Hospitals, involving 100 axSpA patients. Patients were assessed using the Ankylosing Spondylitis Disease Activity Score (ASDAS), Bath Ankylosing Spondylitis Disease Activity Index (BASADI), Bath Ankylosing Spondylitis Functional Index (BASFI), Visual Analogue Scale (VAS), and Katz ADL index. Data on demographics, clinical manifestations, radiological and laboratory findings, and treatment received were collected.

Results: The study included a predominantly male cohort (82%) with an average age of 33.18 years. Key findings include a high prevalence of inflammatory lower back pain, limited spinal involvement, and moderate disease activity as indicated by ASDAS and BASFI scores. Gender-specific analysis revealed no significant differences in clinical, radiological, and serological features between men and women. Treatment primarily involved NSAIDs, DMARDs, and physiotherapy.

Conclusion: This study underscores the need for improved awareness and understanding of axSpA, particularly in recognizing and managing the disease in women. It highlights the necessity of targeted education for healthcare providers, deeper investigation into gender differences in axSpA, and the importance of gender-specific clinical trials.

Keywords: Axial Spondyloarthritis, Ankylosing Spondylitis, axSpA, unmet needs

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Corresponding Author: **Ebtesam Fayez** **E.mail**: basmakhalaf21@gmail.com

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Introduction:

Ankylosing Spondylitis, once considered a distinct disease, is recognized as part of a broader spectrum known as axial spondyloarthritis (axSpA), which also encompasses non-radiographic axSpA. This reclassification aims to enhance early diagnosis sensitivity, reduce diagnostic delays, and facilitate prompt treatment initiation. [1, 2]

Despite improvements in recognition, patient management, and treatment strategies, significant unmet needs remain. Notably, a substantial diagnostic gap of 5-8 years persists from symptom onset to axSpA diagnosis. [3, 4]

Our study aims to enhance awareness and understanding of axSpA, focusing on the current unmet needs in axSpA, especially in the Egyptian context. The gaps in care for axSpA patients include delayed diagnosis, particularly in women, failure to achieve treatment targets, pain, impaired quality of life, and associated comorbidities. [1, 5]

This study is potentially the first to highlight these unmet needs for **ax**SpA patients in Egypt, particularly in Upper Egypt, and aims to contribute significantly to the understanding and management of this condition in this specific population.

Patients and methods:

Study Design:

This observational, cross-sectional, hospital-based study was conducted at the Rheumatology Department at Sohag University Hospitals from January 2023 to December 2023. Ethical considerations were paramount, with the research undergoing approval by the Scientific Ethical Committee of Sohag Faculty of Medicine (Soh-Med-22-08-04), and informed written consents were obtained from all participants.

Inclusion Criteria*:*

1. Patients diagnosed with axSpA, fulfilling the Assessment of SpondyloArthritis International Society (ASAS) classification criteria for axSpA. The ASAS criteria have been validated and are widely implemented for research and diagnostic purposes. [6, 7]
2. Age above 16 years.
3. Patient cooperative and capable of answering questions.

Exclusion Criteria*:*

1. Presence of other rheumatologic or collagen diseases.
2. Age below 16 years and above 60 years.
3. Uncooperative patients.

Methods of the Study:

The study included 100 patients diagnosed with Ankylosing Spondylitis. The assessment tools used were Ankylosing Spondylitis Disease Activity Score (ASDAS), Bath Ankylosing Spondylitis Disease Activity Index (BASADI), Bath Ankylosing Spondylitis Functional Index (BASFI), Visual Analogue Scale (VAS), and Katz ADL index. These tools have been shown to be effective in measuring disease activity and functional status in axSpA patients. [8]

Data Collection:

The study collected the following details:

- Demographic data: age, sex, marital status, occupation, smoking status, and residence.
- Time of diagnosis: categorized as delayed or early.
- Duration of disease.
- Clinical manifestations.
- Radiological data (X-ray and MRI).
- Laboratory tests (ESR, CRP, ANA, RF).
- Treatment received by the patient.
- Comorbidities such as hypertension, diabetes, renal impairment, smoking, etc.

Statistical analysis:

- Data were fed to the computer and analyzed using IBM SPSS software package version 25.0 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp).
- Quantitative data presented as mean ± standard deviation and compared using the Student's t-test.
- Chi-square test employed to compare percentages of qualitative variables.
- We considered p value < 0.05 is significant.

Results:

The study involved 100 axSpA patients with an average age of 33.18 years (SD = 9.40), ranging from 18 to 57 years. The majority of the participants

were male (82%), while females constituted 18% of the sample. Body Mass Index (BMI) averaged 27.01 kg/m^2 (SD = 2.71). (Table 1)

In terms of clinical examination, all participants (100%) exhibited inflammatory lower back pain (LBP). Limited spinal involvement was observed in 64% of the cases (63.4% among males and 66.7% among females). Morning stiffness was reported in 28% of participants. Regarding the duration of morning stiffness, 54% had less than 30 minutes and 18% has morning stiffness of more than 30 minutes. Deformities like loss of lumbar lordosis (12%), exaggerated thoracic kyphosis (4%), and inability to extend the neck, with or without X ray findings (28%) and compensatory hip flexion (2%). All of these findings showed non-significant sex differences (P > 0.05) (Table 2).

X-ray and MRI were utilized to evaluate the participants. On X-rays, sacroiliitis was noted in 53% of the cases, with a higher occurrence in males (56%) compared to females (49%), without significant differences. MRI findings indicated sacroiliitis in over 80% of participants, with males showing a slightly higher prevalences compared to females, without significant differences (Table 3).

Serological tests were conducted to identify specific markers. The Rheumatoid Factor (RF) was negative in 98% of cases, while Antinuclear Antibody (ANA) was found in 12% of participants, with convergent prevalence among males (12.2%) and females (11.1%).

Various assessment tools were employed. The average ASDAS was 3.22 (SD = 0.89), indicating moderate disease activity. The BASDAI averaged 4.18 (SD = 1.12), and the BASFI averaged 3.91 (SD = 1.06). The KATZ ADL had a mean score of 5.02 (SD = 0.78), suggesting a moderate level of independence. The VAS for pain averaged 6.45 (SD = 1.33), indicating a moderate to high level of perceived pain (Table 4).

In terms of treatment, 48% of participants received rehabilitation, and 100% were on current or past NSAIDs treatment. Conventional synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) were prescribed to 40% of the cases at some time of their disease course. Regarding biological and target synthetic DMARDs (tsDMARDs); over 81% of the cases received at least one biological and/or tsDMARDs, although only 54% were regular on treatment. Regarding local steroid injection for the sacroiliac joints, 16 cases; all of them were males, received local steroid injection and this was the only significant difference between males and females among the study population data (Table 5).

Table 1: Demographic data of the studied patients

		Cases (n=100)
Age (year)	Mean±SD	33.18±9.40
	Range	18 - 57
Sex	Male	82 (82%)
	Female	18 (18%)
BMI (kg/m^2)	Mean±SD	27.01±2.71

BMI: Body Mass Index; SD: Standard Deviation

Table 2: Clinical examination data of the studied patients

		Sex		Total (n= 100)	Chi square	P value
		Male (n= 82)	Female (n= 18)			
Inflammatory LBP	Yes	82 (100%)	18 (100%)	100 (100%)	0.000	1.000 (NS)
Limited spinal mobility	Yes	52 (63.4%)	12 (66.7%)	64 (64%)	0.034	1.000 (NS)
Morning stiffness	No	22 (26.8%)	6 (33.3%)	28 (28%)	0.406	0.816 (NS)
	<30 minutes	44 (53.7%)	10 (55.6%)	54 (54%)		
	> 30 minutes	16 (19.5%)	2 (11.1%)	18 (18%)		
Deformities	Loss of lumbar lordosis	10 (12.2%)	2 (11.1%)	12 (12%)	0.074	0.786 (NS)
	Exaggerated thoracic kyphosis	4 (4.9%)	0	4 (4%)	0.339	0.881 (NS)
	Inability to extend the neck	24 (29.3%)	4 (22.2%)	28 (28%)	0.363	0.754 (NS)
	Compensatory hip flexion	2 (2.4%)	0	2 (2%)	0.068	0.794 (NS)
Peripheral joint affection		46 (56.1%)	16 (88.9%)	62 (62%)	3.368	0.127 (NS)
Enthesitis		54 (65.9%)	16 (88.9%)	70 (70%)	1.865	0.247 (NS)

LBP: Lower Back Pain; NS: Non-significant

Table 3: Imaging findings of studied patients

		Sex		Total (n= 100)	Chi square	P value
		Male (n= 82)	Female (n= 18)			
X ray sacroiliac joints	**Erosions**	12 (14.6%)	2 (11.1%)	14 (14%)	0.152	0.696 (NS)
	Pseudo-widening	20 (24.4%)	2 (11.1%)	22 (22%)	1.517	0.218 (NS)
	Ankylosis	14 (17.1%)	3 (16.7%)	17 (17%)	0.093	0.760 (NS)
X ray spine	**Romanus lesion**	2 (2.4%)	0	2 (2%)	0.068	0.794 (NS)
	Bamboo sign	4 (4.9%)	1 (5.6%)	5 (5%)	0.228	0.633 (NS)
	Syndesmophytes	22 (26.8%)	4 (22.2%)	26 (26%)	0.011	0.916 (NS)
	Trolley track	4 (4.9%)	0	4 (4%)	0.085	0.771 (NS)
MRI sacroiliac joints	**Bone marrow edema**	36 (43.9%)	6 (33.3%)	42 (42%)	0.677	0.411 (NS)
	Enthesitis	2 (2.4%)	0	2 (2%)	0.068	0.794 (NS)
	Capsulitis	4 (4.9%)	0	4 (4%)	0.085	0.771 (NS)
	Erosion	10 (12.2%)	2 (11.1%)	12 (12%)	0.074	0.786 (NS)
	Sclerosis	14 (17.1%)	2 (11.1%)	16 (16%)	0.390	0.532 (NS)
	Fat deposition	18 (22%)	2 (11.1%)	20 (20%)	1.084	0.298 (NS)
	Ankylosis	4 (4.9%)	0	4 (4%)	0.085	0.771 (NS)

MRI: Magnetic Resonance Imaging; NS: Non-significant.

Table 4: Distribution of studied patients regarding the assessment tools

	Sex		Total (n= 100)	T test	P value
	Male (n= 82)	**Female** (n= 18)			
ASDAS	2.122±0.844	2.171±1.045	2.131±0.872	1.194	0.880 (NS)
BASDAI	2.463±0.706	2.922±1.124	2.546±0.803	1.174	0.269 (NS)
BASFI	3.615±1.208	4.489±1.222	3.772±1.245	1.962	0.056 (NS)
KATZ ADL	4.34±3.78	1.109±0.972	4.24±1.098	1.408	0.166 (NS)
VAS score	36.46±15.01	44.44±13.57	37.90±14.95	1.467	0.149 (NS)

ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; KATZ ADL: Katz Index of Independence in Activities of Daily Living; VAS: Visual Analogue Scale of Pain; NS: Non-significant.

Table 5: Distribution of studied patients regarding treatment

		Sex		Total (n= 100)	Chi square	P value
		Male (n= 82)	Female (n= 18)			
Rehabilitation & physiotherapy		32 (39%)	6 (33.3%)	48 (48%)	0.203	0.652 (NS)
NSAIDs		82 (100%)	18 (100%)	100 (100%)	-	-
DMARDs	**Methotrexate**	12 (14.6%)	4 (22.%)	16 (16%)	0.194	0.660 (NS)
	Sulfasalazine	18 (22%)	6 (33.3%)	24 (24%)	0.517	0.472 (NS)
Steroid local injection		16 (19.5%)	0	16 (16%)	4.181	**0.041 (S)**
Biological and tsDMARDs	**Secukinumab**	28 (34.1%)	5 (27.8%)	33 (33%)	0.271	0.602 (NS)
	Etanercept	18 (22%)	2 (11.1%)	20 (20%)	1.084	0.298 (NS)
	Golimumab	12 (14.6%)	2 (11.1%)	14 (14%)	0.152	0.700 (NS)
	Adalimumab	8 (9.8%)	4 (22.2%)	12 (12%)	2,172	0.140 (NS)
	Baricitinib	2 (2.4%)	0	2 (2%)	0.068	0.794 (NS)
	None	14 (17.1%)	5 (27.8%)	19 (19%)	0.513	0.474 (NS)
Regularity on treatment	**Yes**	46 (56.1%)	8 (44.4%)	54 (54%)	0.807	0.369 (NS)
	No	36 (43.9%)	10 (55.6%)	46 (46%)		

NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; DMARDs; Drug Modifying Anti-Rheumatic Drugs; tsDMARDs: Targeted synthetic DMARDs; NS: Non-significant.

Discussion:

Axial spondyloarthritis (axSpA) is a chronic inflammatory condition that primarily affects the sacroiliac joints and spine, and is also accompanied by peripheral and extra-articular symptoms. While it was traditionally believed to be more prevalent in males, recent studies indicate that there is little difference in its prevalence between sexes. However, differences in disease presentation between males and females may have previously led to underdiagnosis in women. Men with axSpA typically exhibit more structural damage, whereas women experience a higher disease burden due to a greater occurrence of peripheral symptoms, longer diagnostic delays, higher disease activity, and lower treatment efficacy. [9]

It is worth noting that there is a higher prevalence of non-radiographic axial SpA (nr-axSpA) in women, which further complicates the diagnosis. Additionally, women are underrepresented in clinical trials, resulting in a bias towards male classification and management of the disease. [10]

This study emphasizes the importance of increasing awareness among healthcare professionals who are not rheumatologists, as well as the need for further research into sex-related differences in axSpA. The ultimate goal is to enhance clinical and therapeutic management for female patients.

The study was conducted at Sohag University Hospital's Rheumatology outpatient clinic, utilizing an observational cross-sectional design. The study group consisted of 100 patients who had been diagnosed with Ankylosing Spondylitis.

In our study, the majority of cases were males, comprising 82% of the total, while females accounted for only 18% of the cases. The mean age of the study population was 33.2±9.4 years, with a wide age range from 18 to 57 years. However, there were only a small number of cases aged 50 years or older.

Initially, axSpA was considered to predominantly affect males, with early studies estimating a tenfold higher prevalence in men compared to women. However, this gender disparity has diminished over time due to improved diagnostic tools and increased understanding, with recent data suggesting a prevalence ratio for radiographic axial SpA (r-axSpA) ranging from 1.2 to 2:1 in men versus women. On the other hand, the distribution of nr-axSpA is generally more equal between genders. [1, 11, 12]

Reports from a cohort focused on early disease detection indicate that male patients are diagnosed at a younger age compared to females (27.4±7.5 years in males versus 29.5±7.8 years in females). [13]

In our study, there were no significant differences in the prevalence of RF, ANA, and HLA-B27 between males and females.

HLA-B27 carriership is more prevalent in men compared to women, which may contribute to the differing presentation of axSpA between the sexes,

particularly in terms of radiographic progression. HLA-B27 is also associated with a higher likelihood of detecting axSpA through MRI and a better response to treatment. [14]

A study analyzing disease characteristics in 264 women and 231 men with nr-axSpA, as part of the prospective Swiss Clinical Quality Management Cohort, found that compared to men, women had a lower prevalence of HLA-B27. [15]

In our study, we observed variations in disease activity between males and females. Females had somewhat higher activity scores and lower KATZ-ADL score; but with non statistically significant differences.

A study conducted by Mease et al. [9] reported that women with axSpA were more likely to have concomitant diagnoses of depression and fibromyalgia. They also reported higher disease activity, greater functional impairment, and worse quality of life among women.

Another study by Shahlaee et al. [16], found that female axSpA patients had a higher disease burden in terms of disease activity and pain scores. Specifically, females had significantly higher Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores compared to males, with the items fatigue, total back pain, and longer duration of morning stiffness showing the largest differences.

In a study by Tournadre et al. [17], higher Bath Ankylosing Spondylitis Functionality (BASFI) scores were observed in female patients, while other studies did not find any gender differences. Limited available data on the ASDAS showed no gender differences, as reported by Webers et al. [18]

In our study, we did not find significant differences in the degree of pain between males and females based on mean VAS scores and the percentage of participants reporting mild or moderate pain. The T-test value for the mean VAS scores had marginal significance (p=0.149), suggesting some potential differences in pain intensity between males and females without significant difference.

In their 2022 meta-analysis, Son and colleagues explored the impact of fibromyalgia on individuals with axial spondyloarthritis (axSpA). Their findings indicated that axSpA patients co-diagnosed with fibromyalgia reported significantly higher levels of pain, increased disease activity, and a notably poorer quality of life when compared to those without fibromyalgia. Additionally, the study highlighted a gender disparity, with a female-to-male ratio of approximately 3:2 in fibromyalgia patients and 1:3 in non-fibromyalgia patients. Furthermore, the prevalence of HLA-B27 was found to be 45.1% in patients with fibromyalgia, in contrast to 65.6% in those without significant difference. [19]

The study carried out at a single Egyptian hospital comes with certain limitations that must be recognized. First and foremost, the small sample size limits the applicability of the results beyond the immediate context, reducing their relevance to the broader Egyptian populace or other areas. The research's cross-sectional nature also limits its capability to determine causation or observe longitudinal changes in the progression and functional status of the disease. A major drawback is the lack of a control group, which impairs the study's capacity for comparative analysis against the general population or other distinct cohorts. Additionally, the research overlooks potential impacts of variables like socioeconomic and educational backgrounds on disease progression and patient functionality. Acknowledging and understanding these elements is vital for tailoring effective interventions for axSpA patients in Egypt.

Conclusion:

Women with axSpA experience a significant burden of disease resulting from delayed diagnosis and unique clinical manifestations when compared to men. To address this issue, three important areas for improvement have been identified. Firstly, it is essential to enhance healthcare providers' knowledge and awareness of the disease specifically in women. Secondly, there is a need to deepen our understanding of the gender differences in disease presentation and outcomes. Lastly, conducting clinical trials that focus on gender-specific aspects is crucial. Implementing these measures is vital for promoting timely diagnosis and effective management of axSpA in female patients

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