

## Value of Diverse Hematological Markers in Fibromyalgia: A Real-World Study

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### ABSTRACT

**Objective:** The aim of this study is to assess the diagnostic accuracy and potential role in reflecting systemic inflammation of a broad range of blood cell-derived indexes in fibromyalgia (FM). The efficacy of hematological markers, including the systemic immune-inflammation index (SII), systemic inflammation response index (SIRI), and systemic inflammation aggregate index (AISI) in demonstrating systemic inflammation has not yet been investigated in FM.

**Materials and Methods:** Among the 2,829 patients assessed, a total of 502 patients and 90 age- and sex-matched individuals were involved in the study. Demographic characteristics, C-reactive protein, erythrocyte sedimentation rate, and hematological indexes [platelet-lymphocyte ratio (PLR), neutrophil-lymphocyte ratio (NLR), monocyte-lymphocyte ratio (MLR), SII, SIRI, and AISI] were calculated. Laboratory findings were compared between study groups. Receiver operating characteristic (ROC) analysis was utilized to assess their diagnostic potential.

**Results:** Patients had significantly higher SII, SIRI, and AISI values than controls ( $p=0.011$ ,  $p=0.004$ , and  $p<0.001$ , respectively). No significant differences existed in NLR, MLR, and PLR between groups. According to the ROC analysis, SII, SIRI, and AISI exhibited statistically significant accuracy in differentiating FM from controls ( $p=0.010$ ,  $p=0.003$ , and  $p=0.002$ , respectively). However, the area under the curve values (95% confidence interval) of SII, SIRI, and AISI were 0.584 (0.543-0.624), 0.594 (0.553-0.634), and 0.618 (0.569-0.648), respectively.

**Conclusion:** SII, SIRI, and AISI values are higher in FM, reflecting a potentially increased inflammatory status. Yet, their diagnostic performance is below the acceptable level.

**Keywords:** Blood cell count, fibromyalgia, lymphocytes, mediators of inflammation, neutrophils.



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### INTRODUCTION

Fibromyalgia (FM) is one of the most prevalent rheumatic conditions, manifesting as chronic generalized pain, impaired sleep quality, cognitive problems, fatigue, and various comorbidities.<sup>1</sup> FM may occur alone or coexist with other rheumatic conditions such as rheumatoid arthritis, spondyloarthritis, and osteoarthritis.<sup>2</sup> The prevalence of FM is estimated to range from



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approximately 2% to 6%, depending on the diagnostic criteria sets applied by the American College of Rheumatology (ACR).<sup>3,4</sup> Studies in patients with spondyloarthritis showed that the frequency of FM ranged between 11.1% and 38.4%.<sup>2</sup> In patients with rheumatoid arthritis, this frequency ranges between 17.7% and 29%.<sup>5</sup> A recent study revealed that patients with primary Sjögren's syndrome had a 30% frequency of FM.<sup>6</sup> Patients with FM frequently utilize health care services. Despite its clinical and socio-economic importance, there are no certain biomarkers or specific diagnostic methods for FM. However, the etiopathophysiology of FM is still poorly defined and has been a major focus of study.

Abnormal pain signaling (peripheral and central sensitization), environmental triggers, genetic aspects, endocrine factors, and immune-mediated inflammation may play roles in the pathogenesis of FM.<sup>1,7,8</sup> In terms of inflammation, several plasma-derived mediators have been studied, including coagulation factors, complements, and acute phase proteins.<sup>9</sup> Additionally, cell-derived inflammation markers such as interleukins, chemokines, and oxidative radicals have also been investigated.<sup>7</sup> Furthermore, signs of inflammation can be determined via a hemogram, an easily accessible and inexpensive laboratory test. Several studies have shown the role of hemogram-derived indexes in inflammatory rheumatic conditions, including rheumatoid arthritis, ankylosing spondylitis, and vasculitides.<sup>10–12</sup> For instance, it was observed that patients diagnosed with rheumatoid arthritis exhibited considerably higher ratios of platelet/lymphocyte (PLR), neutrophil/lymphocyte (NLR), and monocyte/lymphocyte (MLR) in comparison to groups of healthy controls.<sup>13</sup> NLR was suggested as a promising inflammatory marker in FM.<sup>14</sup> Research on recently established indexes, the aggregate index of systemic inflammation, systemic immune-inflammation index, and systemic inflammation response index, has been relatively less studied. As far as we are concerned, the capability of these indexes to assess the inflammatory status of FM has not previously been demonstrated.

There is still a need to investigate the profile of inflammatory cell indexes in FM. This case-controlled study was aimed at investigating the diagnostic accuracy of a broad range of hematological indexes in a large sample of FM.

## MATERIALS AND METHODS

### Study Design

All information of participants was obtained from the database system of a tertiary hospital. The University Ethics Committee endorsed the protocol (Approval date and no: September 16, 2022 and 125/77). Informed consent was not required in accordance with the retrospective design.

## KEY MESSAGES

- SII, SIRI, and AISI values are higher in patients with FM than in controls.
- SII, SIRI, and AISI reflect a potentially increased inflammatory status in FM.
- The diagnostic performance of these indexes is below the acceptable level.

The data of 2,829 patients diagnosed with FM in our outpatient clinic between September 2012 and August 2022 were screened. Of them, 502 participants who met the inclusion criteria were involved. Also, 90 age- and sex-matched individuals who applied to our outpatient clinic for nonspecific painful conditions or a general health examination were enrolled.

### Eligibility Criteria

Patients diagnosed with FM according to the ACR 1990 classification criteria, 2010 and/or 2016 diagnostic criteria, aged  $\geq 18$  and  $< 65$  years, and providing concurrent hemogram, C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR) values in the hospital database were included.<sup>15–17</sup>

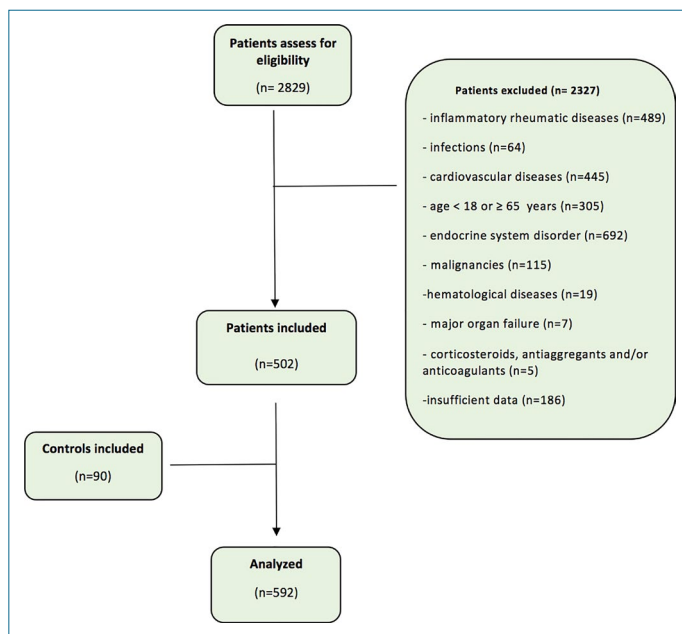
The exclusion criteria included acute and/or chronic infections, co-existing inflammatory rheumatic diseases, endocrine system disorders, malignancies, hematological diseases, cardiovascular diseases, chronic kidney, and liver diseases.

### Demographic and Laboratory Data

Demographic findings (age and gender), medications, and laboratory investigations were recorded in the study groups. Inflammatory hematological ratios and indexes, including NLR, PLR, MLR, SII, SIRI, and AISI, were computed using specific formulas.

### Statistical Analysis

The data analysis was conducted utilizing SPSS 26.0 (IBM Corp., Armonk, NY, USA). The normality of the data was evaluated by multiple methods (the Kolmogorov-Smirnov test and histograms). After checking the normality of the data, the Mann-Whitney U test was used to compare the continuous variables between the groups and presented as medians [25% (Q1)–75% (Q3) quartiles]. The results of comparing categorical variables using Pearson's chi-squared test were presented as numbers (percentages). The correlation between hematological markers was evaluated with Spearman's correlation analysis. The receiver operating characteristics curve was employed to determine the sensitivity, specificity, and threshold values of SII, SIRI, and AISI using MedCalc



**Figure 1.** Flowchart of the study.

statistical software 12.2.1 (MedCalc Inc., Mariakerke, Belgium) based on patient and control groups. Receiver operating characteristic analysis assessed the ability of SII, SIRI, and AISI to discriminate between patients with FM and controls. Acceptable discrimination (area under the curve [AUC]=0.7 to 0.8), excellent discrimination (AUC=0.8 to 0.9), and outstanding discrimination (AUC >0.9) were determined based on the levels of AUC.<sup>18</sup> A p-value of <0.05 was considered statistically significant.

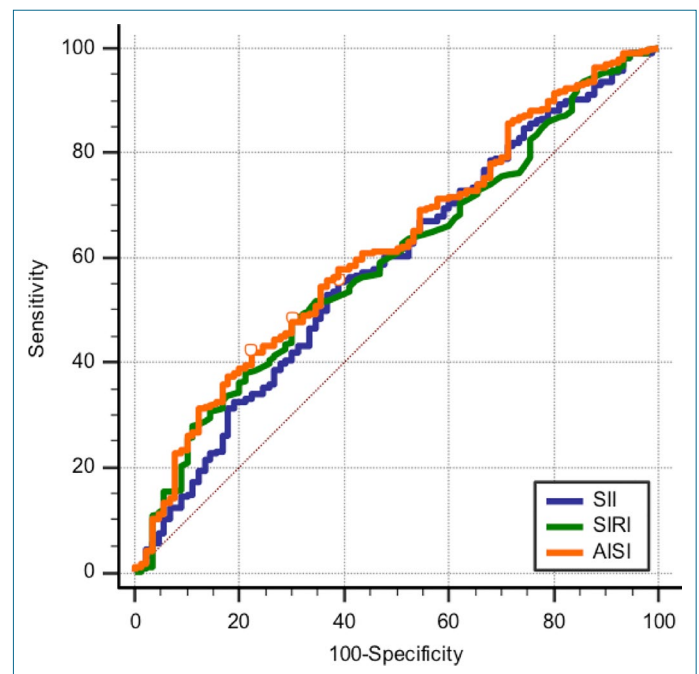
## RESULTS

### Descriptive Analysis

A total of 2,829 patients were assessed for study eligibility. After applying the exclusion criteria, 502 patients with FM and 90 healthy controls were studied (Fig. 1). The median values of age (years) were 44.5 (37–54) in patients and 44 (37–49.3) in controls. The frequencies of the female gender were 84.5% and 84.4% in patients and controls, respectively. Demographic variables (age and gender) did not differ significantly between groups ( $p=0.317$  and  $p=0.997$ , respectively) (Table 1).

### Comparative Analysis of Laboratory Findings

The comparative analysis revealed that CRP, ESR, and blood cell counts were statistically higher in the patients with FM ( $p<0.01$ ) (Table 1). The NLR, MLR, and PLR values between groups did not show a difference. However, SII, SIRI, and AISI in patients with FM were significantly higher than in controls ( $p<0.05$ ) with large effect sizes (Cohen  $d=1.586$ ).



**Figure 2.** Receiver operating characteristic (ROC) curves for the systemic immune inflammation index (SII), systemic inflammation response index (SIRI), and aggregate index of systemic inflammation (AISI) to distinguish patients with fibromyalgia (FM) from controls.

### Correlation Analysis

The potential correlation of the investigated indexes with CRP and ESR was evaluated. There was no correlation between CRP and hematological indexes, including NLR, MLR, PLR, SII, SIRI, and AISI ( $r_s=0.002$ ,  $p=0.965$ ;  $r_s=-0.035$ ,  $p=0.440$ ;  $r_s=0.017$ ,  $p=0.711$ ;  $r_s=0.054$ ,  $p=0.224$ ;  $r_s=0.007$ ,  $p=0.870$ ;  $r_s=0.044$ ,  $p=0.329$ , respectively). There was also no correlation between ESR and these hematological indexes ( $r_s=-0.014$ ,  $p=0.757$ ;  $r_s=0.000$ ,  $p=0.999$ ;  $r_s=0.083$ ,  $p=0.062$ ;  $r_s=0.069$ ,  $p=0.120$ ;  $r_s=0.005$ ,  $p=0.911$ ;  $r_s=0.068$ ,  $p=0.129$ , respectively). The correlation between CRP and ESR was weak ( $r_s=0.277$ ,  $p<0.001$ ).

### ROC Analysis of SII, SIRI, and AISI to Discriminate Between FM and Controls

The diagnostic performance of SII, SIRI, and AISI was evaluated using ROC analysis (Table 2 and Fig. 2). All three blood cell-derived indexes showed statistically significant accuracy in differentiating FM from controls ( $p=0.010$ ,  $p=0.003$ , and  $p=0.002$ , respectively). However, the AUC values [(95% confidence interval (CI))] of SII, SIRI, and AISI were 0.584 (0.543–0.624), 0.594 (0.553–0.634), and 0.618 (0.569–0.648), respectively. Although the best diagnostic test performance

**Table 1.** Comparison of demographic and laboratory parameters between groups

Variables	FM patients (n=502)	Control group (n=90)	p
Age (years)	44.5 (37–54)	44 (37–49.3)	0.317
Female gender	424 (84.5)	76 (84.4)	0.997
Male gender	78 (15.5)	14 (15.6)	
Medications			
Pregabalin	70 (39.5)		
Duloxetine	79 (44.6)		
Venlafaxine	4 (2.3)		
Tricyclic antidepressant	2 (1.1)		
Others	22 (12.4)		
CRP (mg/L)	3.19 (1.99–4.75)	2.36 (1.79–3.16)	<0.001
ESR (mm/h)	12 (5–20)	8 (5–14)	0.003
Neutrophil count (x10 <sup>9</sup> /L)	4.22 (3.45–5.30)	3.73 (3–4.52)	<0.001
Lymphocyte count (x10 <sup>9</sup> /L)	2.30 (1.90–2.80)	2.04 (1.79–2.40)	0.002
Monocyte count (x10 <sup>9</sup> /L)	0.52 (0.43–0.66)	0.50 (0.4–0.5)	<0.001
Platelet count (x10 <sup>9</sup> /L)	264 (225.8–300.3)	242 (187.8–284.8)	0.001
NLR (x10 <sup>9</sup> /L)	1.90 (1.49–2.38)	1.76 (1.43–2.21)	0.137
MLR (x10 <sup>9</sup> /L)	0.23 (0.19–0.29)	0.24 (0.19–0.27)	0.326
PLR (x10 <sup>9</sup> /L)	116.7 (91.29–140.32)	113.9 (91.6–147.3)	0.856
SII (x10 <sup>9</sup> /L)	496.4 (362–666.5)	442.5 (315.7–578.4)	0.011
SIRI (x10 <sup>9</sup> /L)	0.99 (0.71–1.45)	0.84 (0.65–1.16)	0.004
AISI (x10 <sup>9</sup> /L)	258.4 (171.9–403.2)	219.2 (134.4–289.5)	<0.001

Values are presented in: n (%) or median (Q1–Q3). FM: Fibromyalgia; CRP: C-Reactive protein; ESR: Erythrocyte sedimentation rate; NLR: Neutrophil to lymphocyte ratio; MLR: Monocyte to lymphocyte ratio; PLR: Platelet to lymphocyte ratio; SII: Systemic Immune Inflammation Index; SIRI: Systemic Inflammation Response Index; AISI: Aggregate Index of systemic inflammation.

was found in AISI, none of the AUC values was above the limit of acceptability (0.70) for diagnostic performance.

## DISCUSSION

A comprehensive analysis of various blood cell-derived markers was performed on a large sample of FM in the current study. Compared to the control group, patients with FM exhibited elevated SII, SIRI, and AISI values. Previous research has documented the effectiveness of these hematological markers in identifying systemic inflammation. However, the relationship of these markers with FM has not yet been investigated.

The immunologic and inflammatory background of FM has been the subject of numerous studies over the last decade. In general, the evidence seems to conflict with the hypothesis that FM is a non-inflammatory rheumatic condition. Inflammation in FM can be related to blood cells or plasma-derived mediators. In terms of blood cells, neutrophils and platelets play central roles in inflammation. Neutrophils secrete several

cytokines, chemokines, and tissue-damaging factors. Platelets serve as positive acute phase reactants and are associated with inflammatory status.<sup>7,19,20</sup> As a significant finding, platelet and neutrophil counts in our patient group were substantially higher than in the control group. This discrepancy can explain the higher values of cell-based indexes in patients with FM. However, reports in the literature are conflicting on this point.<sup>21–23</sup> Ilgun et al.<sup>21</sup> reported that the NLR values of patients with FM and healthy controls did not differ; however, the PLR was lower in patients. On the other hand, Al-Nimer et al.<sup>22</sup> found no difference between FM patients and controls in terms of PLR and lymphocyte/monocyte ratio (LMR), but NLR was higher in the patient group. Accordingly, in the current study, the patient group exhibited significantly higher levels of SII, SIRI, and AISI. Yet NLR, MLR, and PLR showed no difference between the groups. In our opinion, the complexity of the index might determine its accuracy in reflecting inflammatory status. In the formulas for the NLR, MLR, and PLR, the dividend is the number of a single cell type: neutrophil, platelet, or monocyte. On the

**Table 2.** Receiver operating characteristic curve analysis of SII, SIRI, and AISI

	SII	SIRI	AISI
AUC (95% CI)	0.584 (0.543–0.624)	0.594 (0.553–0.634)	0.618 (0.569–0.648)
Cut-off	>471.52	>1.02	>292.38
Sensitivity (%)	55.38	48.21	42.03
95% CI	50.9–59.8	43.8–52.7	37.7–46.5
Specificity (%)	61.11	70	77.78
95% CI	50.3–71.2	59.4–79.2	67.8–85.9
PPV (%)	88.8	90	91.3
95% CI	85.8–91.2	86.6–92.6	87.2–94.0
NPV (%)	19.7	19.5	19.4
95% CI	16.9–22.9	17.1–22.1	17.1–21.6
P value	0.010	0.003	0.002

AUC: Area under the curve; CI: Confidence intervals; PPV: Positive predictive value; NPV: Negative predictive value; SII: Systemic Immune Inflammation Index; SIRI: Systemic Inflammation Response Index; AISI: Aggregate Index of Systemic Inflammation.

other hand, SII, SIRI, and AISI are more complex indexes that include at least two cell types as dividends. Although these were significantly higher in the FM group, their diagnostic role is still questionable.

Despite the conflicting results in the literature, some cell-derived indexes can shed light on the inflammatory condition of patients with FM. However, there are currently no biomarkers available for diagnosing FM or predicting the outcome of FM patients. ROC analysis revealed the statistically significant accuracy of SII, SIRI, and AISI in differentiating FM from controls. However, the AUC values were below 0.7 for all indexes, reflecting the low acceptability of diagnostic performance. To our knowledge, the potential significance of SII, SIRI, and AISI in identifying inflammation among patients with FM has not been reported. However, there are reports on other less complex indexes. For instance, Aktürk et al.<sup>14</sup> found that NLR was higher in a smaller FM sample. Yet, the AUC of NLR was 0.615. Similarly, Karatas et al.<sup>24</sup> reported that the AUC values of NLR, MLR, and PLR were all below the level of acceptable diagnostic performance (0.614, 0.623, and 0.642). A study by Yetişir et al.<sup>25</sup> demonstrated that NLR and PLR values decreased significantly after anti-tumor necrosis factor (TNF)- $\alpha$  treatment compared to pretreatment values in patients with rheumatoid arthritis.

The potential significance of SII, SIRI, and AISI as indicators of inflammation in FM has not yet been documented, as far as we are concerned. On the other hand, these markers have been studied in various inflammatory rheumatic disorders. They were effective in identifying baseline inflammatory status as well as predicting disease outcomes.<sup>11,13,26–31</sup>

### Strengths and Limitations of This Study

The retrospective design, in which there is a lack of data regarding FM severity, quality of life, and arthropometric measurements of patients, is the main limitation of the current study. On the other hand, having the largest sample size so far, this study resulted in minimal selection bias. Moreover, the present trial stands as a real-world study, which is valuable for reaching a heterogeneous group of patients.

### CONCLUSION

The current study's findings may offer novel insights into the potential role of inflammation in FM. Although these findings reflect a potentially increased inflammatory status in FM, the diagnostic performance of the indexes is below the acceptable level. Their role in determining the severity of disease-related variables should be further studied.

**Ethics Committee Approval:** The Cukurova University Clinical Research Ethics Committee granted approval for this study (date: 16.09.2022, number: 125/77).

**Author Contributions:** Concept – AS, ICB, CO, SB; Design – AS, ICB, CO, SB; Supervision – AS, ICB, SB; Resource – AS, ICB, SB; Materials – AS, CO; Data Collection and/or Processing – AS, CO; Analysis and/or Interpretation – AS, ICB, CO, SB; Literature Search – AS, ICB, CO; Writing – AS, ICB; Critical Reviews – AS, ICB, CO, SB.

**Conflict of Interest:** The authors have no conflict of interest to declare.

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

**Use of AI for Writing Assistance:** Not declared.



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