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Research Article

Study on the Diagnostic Value of Two dsDNA Antibodies in Patients with Systemic Lupus Erythematosus

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Abstract

Objective: This study investigates the relationship between serum dsDNA antibody levels and disease activity in systemic lupus erythematosus (SLE) patients. **Design:** Collect SLE and control group specimens, detect double stranded DNA antibodies using ELISA and CLIA respectively, and compare their diagnostic value. **Place & duration of study:** Conducted at the Department of Clinical Laboratory, Affiliated Jinhua Hospital, Zhejiang University School of Medicine, Jinhua, China, from October 2024 to March 2025. **Method:** Serum samples from 115 SLE patients and 56 healthy individuals were collected from October 20th 2024 to March 30th 2025.Anti-dsDNA antibodies were identified through enzyme-linked immunosorbent assay (ELISA) using the EUROIMMUN Anti-dsDNA-NcX kit and chemiluminescence immunoassay (CLIA) with the Shenzhen Yahuilong system.The diagnostic value of both methods was compared by analyzing detection rates and correlation with disease activity. **Result:** In a study of 115 SLE patients, the detection rate of anti-dsDNA NCX in serum was 79.13%, significantly higher by 73.04% compared to anti-dsDNA CLIA (χ^2=1.171, P>0.05).Serum anti-dsDNA NCX antibody levels showed a strong positive correlation with SLE severity (r=0.788, P=0.000).At an anti-dsDNA NCX antibody level of 103.57 IU/ml, the area under the curve is 0.918, with a sensitivity of 79.1% and specificity of 96.2%. The expression level of anti-dsDNA NCX antibodies, undetectable by anti-dsDNA CLIA in SLE patients' serum, was 32.26% (P<0.05). **Conclusion:** Anti-dsDNA NCX antibodies demonstrate a higher positive detection rate for SLE compared to anti-dsDNA CLIA, particularly in cases where anti-dsDNA CLIA results are negative, underscoring their clinical importance.This study provides a new method for the early diagnosis of SLE.

Keywords: Anti-dsDNA NCX antibody; Systemic lupus erythematosus; Enzyme-linked immunosorbent assay (ELISA)

Introduction

Systemic lupus erythematosus (SLE) is an autoimmune disease of unknown etiology, characterized by different clinical manifestations and potential involvement of multiple organs [1].The World Health Organization reports that SLE affects 20 to 150 individuals per 100,000 globally, with significant variations across sex and ethnicity [2].Although the introduction of biologics in the past two decades has significantly improved patient outcomes, early diagnosis and precise treatment of SLE remain major challenges—over 60% of patients present with irreversible organ damage at their initial medical visit [3].The core of this clinical dilemma lies in the absence of a biomarker system that combines high specificity with the ability to dynamically monitor disease progression.

The immunological hallmark of SLE is the aberrant proliferation of autoantibodies.Anti-DNA antibodies, which bind to DNA, are crucial serological markers for diagnosing and assessing the activity of SLE.Among the over 180 autoantibodies linked to SLE, the anti-double stranded DNA (anti-dsDNA) antibody is distinguished by its high specificity (≥ 90% with precise detection methods) and is included in the 2019

ACR/EULAR classification criteria.Numerous studies have shown a strong positive correlation between anti-dsDNA antibody titers and disease activity [6, 7].These antibodies not only reflect immune system dysregulation but also contribute to SLE pathogenesis, such as by forming immune complexes that activate complement, damaging renal podocytes, and disrupting the blood-brain barrier [8].However, such "classical antibodies" exhibit notable limitations.Anti-Smith (anti-Sm) antibodies, although highly specific, have poor sensitivity [9]; anti-dsDNA antibodies, while closely related to disease activity, show wide variation in sensitivity across traditional detection methods [8, 10].The discrepancy stems from fundamental methodological differences: the radioimmunoassay (Farr assay) provides high specificity but poses radioactive risks [11], while the enzyme-linked immunosorbent assay (ELISA) is user-friendly but susceptible to false negatives due to inadequate exposure of antigenic epitopes. To overcome the limitations of traditional detection methods, next-generation immunoassay technologies have gradually been applied in clinical practice [12].Chemiluminescence immunoassay (CLIA) improves the detection sensitivity of anti-dsDNA antibodies to 75% by optimizing antigen coating procedures [13]; however, its ability to detect low-affinity antibodies remains controversial.In recent years, the introduction of nucleosome bridging technology has offered a novel approach to addressing this issue.This technique utilizes chromatin core particles, which include the histone H2A-H2B complex, to mimic the natural conformation of dsDNA [14], allowing antibody-antigen interactions to more closely resemble physiological conditions in vivo.Preliminary studies have shown that NCX-ELISA improves the additional diagnostic rate in seronegative SLE patients [15]; however, the lack of standardization across different detection platforms continues to hinder its clinical translation.

Due to the diverse clinical presentations of SLE and the critical importance of serological testing in managing the disease, identifying antibody biomarkers that accurately indicate disease activity is essential for enhancing SLE diagnosis and treatment.This study examines the relationship between serum anti-dsDNA antibody levels and disease activity in SLE patients, assessing their potential utility in monitoring and personalized management.The study systematically evaluates and compares the expression patterns and diagnostic significance of anti-dsDNA-NcX and anti-dsDNA CLIA antibodies in SLE patients, elucidating their association with disease activity and supporting precision medicine strategies.

Object and Method

Object

Systemic lupus erythematosus (SLE) is characterized by the presence of over 180 distinct autoantibodies in the serum of patients.This research was structured as a prospective case-control study with a cross-sectional design.From October 2024 to March 2025, a total of 115 SLE patients admitted consecutively to Jinhua Central Hospital were enrolled according to their order of admission.The study included 115 participants, comprising 109 females and 6 males, with an average age of 42.2 ± 13.6 years.The diagnosis adhered to the 2019 SLE classification criteria set by the American College of Rheumatology (ACR) [5].There were 56 healthy individuals who underwent physical examinations from the health examination center.The gender and age distribution of the research subjects are shown in Table 1, and detailed clinical characteristics are provided in Table S1.In the morning, four milliliters of venous blood were drawn from each fasting patient.Samples were clotted at room temperature for 1 hour and then centrifuged at 3,000 rpm for 5 minutes at 4°C to isolate the serum.The serum was divided into aliquots and stored at −80 °C for later use.

The Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) [16] was utilized to quantify disease activity. Evaluations were independently performed by two attending physicians, each with over 10 years of experience in rheumatology.All assessments were conducted in a blinded manner, with evaluators having no access to patients' laboratory results.All data were double-entered and validated using the REDCap electronic data management system to ensure traceability and data integrity.

The Medical Ethics Committee of Jinhua Central Hospital (Jinhua, Zhejiang Province, China; postal code 321000) approved this study under approval number (Res)2024-Ethics Review-182 on October 15, 2024.Informed consent was not obtained from any participants.

disease	Number of cases	Gender (Male/Female)	age
SLE	115	6/109	42.2 ± 13.6
RA	31	3/32	62.2± 11.0
SSC	20	2/18	60.6 ± 11.0
SS	8	1/7	53.9 ± 16.0
healthy individuals	56	16/40	30.5 ± 6.2

Table 1 Gender and Age Distribution of Research Subjects

Variable	SLE (n = 115)	Healthy Controls (n = 56)
Gender	Male 6 (5.2 %) Female 109 (94.8 %)	Male 28 (50.0 %) Female 28 (50.0 %)
Age (years)	42.2 ± 13.6	41.0 ± 12.8
Disease duration (years)	8.0 [1.0-9.5]	-
Receiving glucocorticoids	102 (90.3 %)	0
Receiving immunosuppressants	102 (90.3 %)	0
ANA titer	1: 1280 [1: 640-1: 2560]	1: 80 [1: 40-1: 120]
CRP (mg/L)	0.8 [2.1]	0.6 [0.5]
ESR (mm/h)	18 [19.0]	9 [6.0]
WBC (×10^9/L)	5.45 [3.32]	6.4 [2.0]
anti-dsDNA NcX positive[1]	91 (79.1 %)	0 (0)
anti-dsDNA CLIA positive[2]	84 (73.0 %)	0 (0)

NcX = anti-dsDNA-NcX ELISA; CLIA = anti-dsDNA-CLIA. [1] Positive threshold for NcX: ≥ 100 IU/mL; [2] Positive threshold for CLIA: ≥ 30 IU/mL.

Table S1 Baseline Demographic and Laboratory Characteristics of Study Participants

Inclusion and Exclusion Criteria

All patients satisfied the 2019 SLE classification criteria set by the American College of Rheumatology (ACR) [5]. Inclusion criteria included: (1) at least one clinical criterion, such as biopsy-confirmed lupus nephritis or active cutaneous lupus with a SLEDAI score of 8 or higher; (2) meeting immunological criteria, such as anti-dsDNA antibody levels exceeding 30 IU/mL or a positive anti-Sm antibody; and (3) achieving a total score of 10 or more based on a weighted point system, where clinical criteria are assigned 2–8 points and immunological criteria 4–6 points.

Exclusion criteria comprised concurrent autoimmune diseases (excluding rheumatoid arthritis and Sjögren's syndrome as per references [17] and [18]), recent treatment with biologics like belimumab or high-dose immunosuppressants (prednisone >0.5 mg/kg/day) within the last 3 months, active infections (C-reactive protein >10 mg/L and procalcitonin ≥ 0.5 ng/mL), malignancies, and pregnancy.

In addition, 56 healthy individuals from the health examination center were included as the control group.Participants were selected based on the absence of autoantibodies (ANA titer < 1:80 and anti-dsDNA antibody ≤ 30 IU/mL), no history of acute infections or recent vaccinations, and no history of immunodeficiency disorders or use of immunomodulatory medications [19].

Instruments and Reagents

The anti-dsDNA NCX antibody ELISA kit, batch number E231220AI, was obtained from Omon Medical Laboratory Diagnostics GmbH, Germany. The anti-dsDNA CLIA antibody chemiluminescence detection kit and instrument iFlash3000 were purchased from Shenzhen Yahuilong Biotechnology Co., Ltd; The fully automatic blood cell analyzer BC7500 and its supporting reagents were purchased from Shenzhen Mindray Medical Electronics Co., Ltd; The ELISA instrument PHOMO was purchased from Zhengzhou Antu Experimental Instrument Co., Ltd; The washing machine BIOTEK ELX50 was purchased from Boten Corporation in the United States.

Method

Detection of Anti-dsDNA-NcX Antibodies by ELISA: We used the Anti-dsDNA-NcX ELISA (IgG) kit (Cat.No.EA1572-9601G) from EUROIMMUN AG to detect anti-dsDNA-NcX antibodies.This kit utilizes a high-purity complex of natural dsDNA and nucleosomes as antigens to enhance detection specificity and sensitivity.Serum samples were diluted 1:200, with 100 µL of each added to the microwell plate and incubated with the antigen at room temperature for 30 minutes, using standards provided by the kit.Following three washes, an enzyme-linked secondary antibody was added and incubated for 30 minutes at room temperature in the dark.After three more washes, the substrate solution was introduced, and the reaction was halted after 15 minutes.Absorbance (A value) was measured using a PHOMO microplate reader.All procedures were conducted and verified following the manufacturer's guidelines.A concentration of anti-dsDNA-NcX antibody ≥100 IU/mL was considered positive.

Detection of Anti-dsDNA-CLIA Antibodies by CLIA: Anti-dsDNA antibodies were also detected using a commercial CLIA kit.Specifically, the Anti-dsDNA CLIA kit (Cat.No.310440) from Shenzhen Yahuilong.It was used in conjunction with the fully automated chemiluminescence analyzer.All procedures were meticulously followed as per the manufacturer's guidelines provided with the kit.All reagents were validated and quality-controlled as per the manufacturer's specifications.A concentration of anti-dsDNA-CLIA antibody ≥ 30 IU/mL was

considered positive.
White blood cell count, erythrocyte sedimentation rate, and C-reactive protein were measured using a fully automated BC7500 hematology analyzer.

Statistical Processing
Statistical analysis was performed using SPSS 21.0 for Windows.Inc., Chicago, IL) software.The χ^2 test was employed to compare the positive rates of anti-dsDNA NCX and anti-dsDNA CLIA antibodies, while Pearson correlation analysis was used to examine the relationship between these antibodies and the SLEDAI score.The diagnostic efficacy of antibodies was evaluated via receiver operating characteristic (ROC) curve analysis, identifying the maximum Youden index as the optimal threshold to derive metrics like area under the ROC curve (AUC), sensitivity, and specificity.The difference is statistically significant with a p-value less than 0.05.

Results

Comparison of positivity rates of anti-dsDNA NCX antibody and anti-dsDNA CLIA antibody
In 115 SLE patients, the anti-dsDNA NCX antibody showed a positive rate of 79.13%, surpassing the anti-dsDNA CLIA antibody's rate of 73.04% (χ^2=1.171, P>0.05). The combined detection of both antibodies yielded a positive rate of 81.74%, also higher than the 73.04% rate of the anti-dsDNA CLIA antibody alone (χ^2=2.485, P>0.05), as detailed in Table 2.

project	Number of cases	Positive rate %
Positive anti ds DNA NCX antibody	115(91)	79.13
Positive anti ds DNA CLIA antibody	115(84)	73.04
Positive for anti ds DNA NCX antibody+anti ds DNA CLIA antibody	115(94)	81.74
$\chi 1^2$		1.171
$\chi 2^2$		2.485
*P*1		0.279
*P*2		0.115

Table 2 Comparison of Positive Rates of Anti ds DNA NCX Antibody and Anti ds DNA CLIA Antibody

The $\chi 1^2$P1 value represents the comparison between anti-dsDNA NCX antibody and anti-dsDNA CLIA antibody; The $\chi 2^2$P2 value of represents the comparison between the combined detection of two antibodies and the anti-dsDNA CLIA antibody
Diagnostic efficacy of anti-dsDNA NCX antibodies and anti-dsDNA CLIA antibodies in SLE
Using statistical software SPSS 21.0 to plot ROC curves, with disease activity period as the reference variable, the highest cutoff point in the upper left corner is taken for each curve.At this point, the sum of sensitivity and specificity is the highest, and the diagnostic value is the highest.At the upper left corner inflection points, the anti-dsDNA NCX antibody at 103.57 IU/ml shows an AUC of 0.918 with 79.1% sensitivity and 96.2% specificity. The anti-dsDNA CLIA antibody at 28.3 IU/ml has an AUC of 0.907, with sensitivity and specificity of 73.9% and 97.5%, respectively. For ESR at 16.5 mm/h, the AUC is 0.515, with 53.0% sensitivity and 53.2% specificity. CRP at 1.12 mg/l yields an AUC of 0.424, with sensitivity and specificity of 42.6% and 54.4%, respectively. Finally, WBC at 6.76*10^9/L results in an AUC of 0.434, with 33.0% sensitivity and 64.6% specificity.Refer to Table 3 and Figure 1.

	AUC	Optimal critical value	sensitivity (%)	specificity (%)	95% confidence interval		P
					lower limit	upper limit	
Anti-dsDNA NCX antibody	0.918	103.57	79.1	96.2	0.878	0.957	0.000
Anti-dsDNA CLIA antibody	0.907	28.3	73.9	97.5	0.866	0.948	0.000
WBC	0.434	6.76	33.0	64.6	0.352	0.515	0.116
CRP	0.424	1.12	42.6	54.4	0.343	0.506	0.074
ESR	0.515	16.5	53.0	53.2	0.428	0.601	0.726

Table 3 Diagnostic efficacy of anti-dsDNA NCX antibody and anti-dsDNA CLIA antibody in SLE

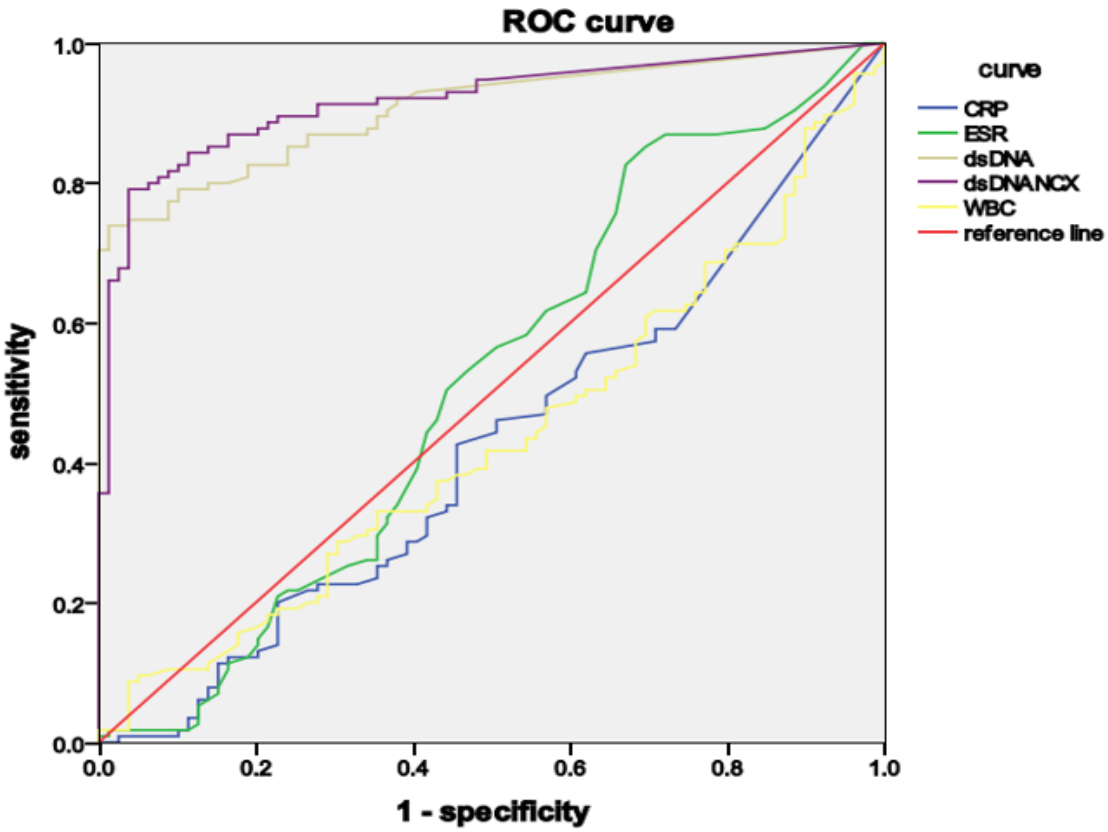

Figure 1 Receiver operating characteristic (ROC) evaluation of the diagnostic efficacy of anti-dsDNA NCX antibodies and anti ds DNA CLIA antibodies for SLE

Relationship between anti-dsDNA NCX antibody and anti-dsDNA CLIA antibody

Next, we analyzed the proportion of patients among the 115 SLE cases who tested positive by only one of the two detection methods, without overlap.The positive rate for anti-dsDNA-NcX antibodies alone was 8.70%, while that for anti-dsDNA-CLIA antibodies alone was 2.61%.The difference between the two was statistically significant ($\chi 2$= 3.995, P <0.05).The positivity rate of anti-dsDNA NCX antibodies in SLE with negative anti-dsDNA CLIA antibodies is 32.26%. The findings suggest that identifying anti-dsDNA NCX antibodies is clinically significant, particularly for SLE patients who test negative for anti-dsDNA CLIA antibodies.See Table 4.

project	Number of cases	Positive rate %
Single anti-dsDNA NCX antibody positive	10	8.70
Single anti-dsDNA CLIA antibody positive	3	2.61
Positive for anti-dsDNA NCX antibody+anti-dsDNA antibody	94	81.74
$\chi 2$		3.995
P		0.046

Table 4 Relationship between anti-dsDNA NCX antibodies and anti-dsDNA CLIA antibodies in 115 cases of SLE

$\chi 2$ P : Comparison between anti-dsDNA NCX antibody and anti-dsDNA CLIA antibody

Correlation analysis between anti-dsDNA NCX antibody, anti-dsDNA CLIA antibody and SLEDAI score

In 91 SLE patients with positive anti-dsDNA NCX antibodies, the concentration level of anti ds DNA NCX antibodies was moderately positively correlated with SLEDAI (r=0.782, P=0.000).The higher the concentration of anti-dsDNA NCX antibodies, the higher the SLEDAI score, indicating higher disease activity in SLE.In 76 SLE patients with positive anti-dsDNA CLIA antibodies, the concentration level of anti-dsDNA CLIA antibodies was moderately positively correlat-

ed with SLEDAI (r=0.788, P=0.000).The higher the concentration of anti-dsDNA CLIA antibodies, the higher the SLEDAI score, indicating higher disease activity in SLE.

Discussions

SLE is a systemic autoimmune disease that affects multiple organs and functions.It is a serious disease that endangers human health, often accompanied by damage to multiple organs such as the kidneys, skin, and blood, and can affect the central nervous system [20].At present, the clinical diagnosis and treatment of SLE are based on immunology, and their diagnosis and treatment have been included in clinical guidelines.Anti-dsDNA antibodies are key immunological markers that significantly influence the onset and progression of SLE [21].As the disease progresses, their antibody titers gradually decrease until they turn negative [22].Research indicates that anti SSA antibodies are initially produced in SLE patients and can be detected up to two years prior to diagnosis [23].This cross-sectional study systematically assessed the performance of NCX-ELISA and CLIA methods for detecting anti-dsDNA antibodies in diagnosing SLE and evaluating disease activity.The results indicated a correlation between serum anti-dsDNA-NcX antibody levels and SLEDAI scores, as well as an association with corresponding levels of drug-induced antibodies.

This study revealed that anti-dsDNA-NcX antibodies outperformed anti-dsDNA-CLIA antibodies in diagnosing SLE, showing enhanced sensitivity and adequate specificity.The results indicate that the NCX detection method could offer enhanced clinical utility.Compared with the sensitivity of 75% and specificity of 90.5% reported by Ohnuma K et al.at a cutoff value of 40 IU/mL [24], and the sensitivity of 60.9% and specificity of 98.9% reported by Biesen R et al.at a cutoff of 100 IU/mL [14], the threshold of 103.57 IU/mL used in our study further optimized diagnostic performance, achieving a sensitivity of 79.1% and a specificity of 96.2%.It is noteworthy that differences in results across studies may be attributed to heterogeneity in study populations, varying disease activity states, and differences in the degree of platform standardization.Our study improved reproducibility and representativeness by rigorously selecting SLE patients according to the 2019 ACR-EULAR classification criteria and utilizing standardized procedures alongside a quality control system.We conducted a parallel comparison of both anti-dsDNA antibody detection methods within the same population, enhancing the study's scientific rigor and practical relevance.

The anti-dsDNA antibody is a specific autoantibody in SLE, correlating with the disease's severity.However, some SLE patients may experience exacerbation of the disease when anti-dsDNA antibodies are not detected.In our study, among SLE patients who were seronegative for anti-dsDNA-CLIA antibodies, the expression level of anti-dsDNA-NcX antibodies was 32.26%, indicating that the NCX assay may compensate for the false-negative results of CLIA.This finding aligns with the viewpoint proposed by Egner et al.Their review indicated that utilizing multiple platforms may improve the detection rate of autoantibodies in SLE [25].This has important clinical value for SLE patients, particularly those who are seronegative for anti-dsDNA-CLIA antibodies.

This single-center, prospective cross-sectional observational study has several limitations: (1) A limited sample size, particularly in disease control groups like RA and SS, which may affect statistical power; (2) Selection bias due to the inclusion of only consecutively admitted patients from a single tertiary hospital, restricting the generalizability of findings to other regions and primary care settings; (3) The cross-sectional design precludes establishing causality, allowing only inference of correlation between NCX and CLIA detection performance; (4) Absence of longitudinal follow-up, preventing assessment of the platforms' dynamic value in monitoring disease activity; (5) The diagnostic threshold was based on the ROC curve from this cohort without multicenter validation.These factors may affect the robustness of the conclusions, and further confirmation is needed in larger, multicenter prospective cohorts.

Conclusion

This research employed a prospective cross-sectional case-control design to evaluate and compare the performance of anti-dsDNA-NcX ELISA and anti-dsDNA-CLIA in the same patient cohort.The NcX assay demonstrated greater sensitivity than CLIA, successfully identifying antibodies in a subset of SLE patients who were CLIA-negative.The anti-dsDNA-NcX antibody titer was positively correlated with SLEDAI scores, suggesting its potential utility in monitoring disease activity.The study also identified an optimal NcX cutoff value specific to the local population, providing a basis for laboratory standardization.Given the limited sample size and single-center design, these findings require further validation in larger, multicenter studies.

Author Declarations

Consent

Informed consent was obtained from all participants before sample collection.

Ethical Considerations

The Ethics Committee of Jinhua Central Hospital reviewed and approved the study protocol (Approval No.).(Res)2024-Ethics Review-182).All procedures adhered to the Declaration of Helsinki.

Conflict of Interest

The authors state they have no conflicts of interest.

Author Contributions

Conceptualization: Dong Feng; Methodology: Dong Feng, Wang Limin; Investigation and Data Curation: Dong Feng. Gong Rui; Formal Analysis: Wang Limin; Writing—Original Draft: Dong Feng; Writing—Review & Editing: Wang Limin; Supervision and Project Administration: Wang Limin.All authors have reviewed and approved the final version of the manuscript for publication.

Data Availability

The datasets from this study can be obtained from the corresponding author upon reasonable request.

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References

1. Kiriakidou M, Ching CL. Systemic Lupus Erythematosus. Ann Intern Med. 2020;172(11):ITC81-ITC96. doi:10.7326/AITC202006020
2. Appleton, Brenna D., and Amy S. Major. "The latest in systemic lupus erythematosus-accelerated atherosclerosis: related mechanisms inform assessment and therapy." *Current opinion in rheumatology* 33, no. 2 (2021): 211-218.
3. Hoi A, Igel T, Mok CC, Arnaud L. Systemic lupus erythematosus [published correction appears in Lancet. 2024 May 25;403(10441):2292. doi: 10.1016/S0140-6736(24)01044-4.]. Lancet. 2024;403(10441):2326-2338. doi:10.1016/S0140-6736(24)00398-2
4. Yaniv, Gal, Gilad Twig, Dana Ben-Ami Shor, Ariel Furer, Yaniv Sherer, Oshry Mozes, Orna Komisar et al. "A volcanic explosion of autoantibodies in systemic lupus erythematosus: a diversity of 180 different antibodies found in SLE patients." *Autoimmunity reviews* 14, no. 1 (2015): 75-79.
5. Aringer, Martin, Karen Costenbader, David Daikh, Ralph Brinks, Marta Mosca, Rosalind Ramsey-Goldman, Josef S. Smolen et al. "2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus." *Arthritis & rheumatology* 71, no. 9 (2019): 1400-1412.
6. Pisetsky, David S. "Anti-DNA antibodies—quintessential biomarkers of SLE." *Nature Reviews Rheumatology* 12, no. 2 (2016): 102-110.
7. Shamim, Roshila, Sumaira Farman, Shabnam Batool, Saira Elaine Anwer Khan, and Muhammad Kamil Hussain Raja. "Association of systemic lupus erythematosus disease activity index score with clinical and laboratory parameters in pediatric onset systemic lupus erythematosus." *Pakistan Journal of Medical Sciences* 36, no. 3 (2020): 467.
8. Lou, Hantao, Guang Sheng Ling, and Xuetao Cao. "Autoantibodies in systemic lupus erythematosus: From immunopathology to therapeutic target." *Journal of autoimmunity* 132 (2022): 102861.
9. Parodis, Ioannis, Emil Åkerström, Christopher Sjöwall, Azita Sohrabian, Andreas Jönsen, Alvaro Gomez, Martina Frodlund et al. "Autoantibody and cytokine profiles during treatment with belimumab in patients with systemic lupus erythematosus." *International Journal of Molecular Sciences* 21, no. 10 (2020): 3463.
10. Zarmbinski, M. A., R. P. Messner, and J. S. Mandel. "Anti-dsDNA antibodies in laboratory workers handling blood from patients with systemic lupus erythematosus." *The Journal of rheumatology* 19, no. 9 (1992): 1380-1384.
11. Antico, A., S. Platzgummer, D. Bassetti, N. Bizzaro, R. Tozzoli, D. Villalta, and Study Group on Autoimmune Diseases of the Italian Society of Laboratory Medicine (SIMeL). "Diagnosing systemic lupus erythematosus: new-generation immunoassays for measurement of anti-dsDNA antibodies are an effective alternative to the Farr technique and the Crithidia luciliae immunofluorescence test." *Lupus* 19, no. 8 (2010): 906-912.
12. Infantino, Maria, Boaz Palterer, Giulia Previtali, Maria-Grazia Alessio, Danilo Villalta, Teresa Carbone, Stefan Platzgummer et al. "Comparison of current methods for anti-dsDNA antibody detection and reshaping diagnostic strategies." *Scandinavian Journal of Immunology* 96, no. 6 (2022): e13220.
13. He, Shiyi, Xiaoning Wu, Limin Li, Kongmei Jiang, Qitian He, and Li Xie. "A comparison of the chemiluminescence immunoassay and Crithidia luciliae immunofluorescence test in detecting anti-dsDNA antibodies and assessing the activity of systemic lupus erythematosus." *Lupus* 32, no. 8 (2023): 936-941.
14. Biesen, Robert, Cornelia Dähnrich, Anke Rosemann, Fidan Barkhudarova, Thomas Rose, Olga Jakob, Anne Bruns et al. "Anti-dsDNA-NcX ELISA: dsDNA-loaded nucleosomes improve diagnosis and monitoring of disease activity in systemic lupus erythematosus." *Arthritis research & therapy* 13, no. 1 (2011): R26.
15. Abozaid, Hanan Sayed M., Hesham M. Hefny, Esam M. Abualfadl, Mohamad A. Ismail, Amal K. Noreldin, Ahmed N. Nour Eldin, Asmaa M. Goda, and Amal H. Ali. "Negative ANA-IIF in SLE patients: what is beyond?." *Clinical Rheumatology* 42, no. 7 (2023): 1819-1826.
16. Luijten, K. M. A. C., J. Tekstra, J. W. J. Bijlsma, and M. Bijl. "The systemic lupus erythematosus responder index (SRI); a new SLE disease activity assessment." *Autoimmunity reviews* 11, no. 5 (2012): 326-329.

17. Aletaha, Daniel, Tuhina Neogi, Alan J. Silman, Julia Funovits, David T. Felson, Clifton O. Bingham III, Neal S. Birnbaum et al. "2010 rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative." *Arthritis & rheumatism* 62, no. 9 (2010): 2569-2581.
18. Shiboski, S. C., C. H. Shiboski, L. A. Criswell, A. N. Baer, S. Challacombe, H. Lanfranchi, M. Schiødt et al. "American College of Rheumatology classification criteria for Sjögren's syndrome: a data-driven, expert consensus approach in the Sjögren's International Collaborative Clinical Alliance cohort." *Arthritis care & research* 64, no. 4 (2012): 475-487.
19. Attar, Suzan M., and Emad A. Koshak. "Medical conditions associated with a positive anti-double-stranded deoxyribonucleic acid." *Saudi Med J* 31, no. 7 (2010): 781-7.
20. Aringer, Martin, and Sindhu R. Johnson. "Classifying and diagnosing systemic lupus erythematosus in the 21st century." Rheumatology 59, no. Supplement_5 (2020): v4-v11.
21. Alba, P., L. Bento, M. J. Cuadrado, Y. Karim, M. F. Tungekar, I. Abbs, M. A. Khamashta, D. D'cruz, and G. R. V. Hughes. "Anti-dsDNA, anti-Sm antibodies, and the lupus anticoagulant: significant factors associated with lupus nephritis." *Annals of the rheumatic diseases* 62, no. 6 (2003): 556-560.
22. Nossent, Hans C., and Ole Petter Rekvig. "Is closer linkage between systemic lupus erythematosus and anti-double-stranded DNA antibodies a desirable and attainable goal?." *Arthritis Research & Therapy* 7, no. 2 (2005): 85.
23. Arbuckle, Melissa R., Micah T. McClain, Mark V. Rubertone, R. Hal Scofield, Gregory J. Dennis, Judith A. James, and John B. Harley. "Development of autoantibodies before the clinical onset of systemic lupus erythematosus." *New England Journal of Medicine* 349, no. 16 (2003): 1526-1533.
24. Ohnuma, Kenichiro, Nobuhide Hayashi, Noriko Fukuzumi, Asami Saito, Megumi Tanaka, Shunichi Kumagai, and Seiji Kawano. "Evaluation of cut-off value for autoantibodies against double-stranded DNA-complexed nucleosomes based on enzyme linked immunosorbent assay." Rinsho byori. *The Japanese Journal of Clinical Pathology* 62, no. 3 (2014): 223-230.
25. Egner, William. "The use of laboratory tests in the diagnosis of SLE." *Journal of clinical pathology* 53, no. 6 (2000): 424-432.

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