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Association of Systemic Lupus Erythematosus Disease Activity With Multidimensional Reproductive Health Among Iranian Women: A WHO Framework–Based Study

Elham Rezaei

rezai520@yahoo.com

Tabriz University of Medical Sciences

Armin Zareiyan

Aja University of Medical Sciences

Seyedeh Tahereh Faezi

Tehran University of Medical Sciences

Zahra Behboodi Moghadam

Tehran University of Medical Sciences

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Abstract

Reproductive health in women with systemic lupus erythematosus (SLE) is multidimensional and may be influenced by disease activity; however, the association between graded disease activity and comprehensive reproductive health outcomes remains insufficiently characterized. This study examined the association between SLE disease activity and multidimensional reproductive health aligned with the World Health Organization framwork.

This cross-sectional study was conducted between January 2023 and March 2024 among 429 women aged 15–49 years with confirmed SLE recruited from a rheumatology clinic and the Lupus Association. After exclusion of incomplete questionnaires, 400 participants were included in the final analysis. Data were collected using a demographic questionnaire, the Reproductive Health Assessment in Systemic Lupus Erythematosus (RHASLE) instrument, and the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). Associations between disease activity and reproductive health domains were evaluated using Pearson correlation, ANOVA, and multivariable linear regression adjusted for age, disease duration, education, employment, medication use, and comorbid conditions.

Among 400 women (mean age 35.85 ± 5.78 years), the mean total RHASLE score was 368.08 ± 52.58. Compared with mild/moderate disease activity, severe disease activity was independently associated with lower scores in physical–psychological well-being (B = − 18.81, 95% CI: − 32.40 to − 5.23, p = 0.007), sexual satisfaction (B = − 7.07, 95% CI: − 13.61 to − 0.53, p = 0.034), and overall reproductive health (B = − 37.61, 95% CI: − 64.17 to − 11.05, p = 0.006). Silent disease activity was associated with higher physical–psychological well-being (B = 13.79, 95% CI: 4.04 to 23.55, p = 0.006) and overall reproductive health scores (B = 22.14, 95% CI: 3.06 to 41.22, p = 0.023). Regression models explained 23–49% of the variance in reproductive health outcomes.

Higher SLE disease activity is associated with poorer multidimensional reproductive health, particularly physical–psychological well-being and sexual satisfaction. These findings highlight the importance of incorporating reproductive and sexual health assessment into routine SLE management and underscore the potential benefits of disease activity control for improving patient-centered reproductive health outcomes.

Introduction

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease characterized by relapsing–remitting inflammation and multi-organ involvement, disproportionately affecting women of reproductive age and contributing substantially to long-term morbidity [1,2]. Although advances in treatment have improved survival, SLE continues to impose a considerable burden on health-related quality of life, including reproductive health outcomes such as fertility, pregnancy, and sexual functioning [3–5]. Women with SLE can achieve successful pregnancies; however, they remain at increased risk of adverse maternal and fetal outcomes, including miscarriage, preeclampsia, preterm birth, and neonatal lupus [6,7]. Beyond obstetric complications, sexual dysfunction—manifesting as reduced desire, impaired arousal, dyspareunia, and dissatisfaction—has been reported at higher rates in women with SLE compared with the general population. These reproductive challenges are frequently accompanied by psychological distress, altered body image, concerns regarding fertility, and fear of disease transmission to offspring. Together, these findings underscore that reproductive health in SLE extends beyond pregnancy outcomes and encompasses physical, psychological, social, sexual, and spiritual dimensions of well-being, consistent with the World Health Organization (WHO) definition of reproductive health [8].

Despite growing recognition of these issues, much of the existing literature has focused on isolated reproductive outcomes, such as pregnancy complications or sexual dysfunction, rather than evaluating reproductive health as a comprehensive, multidimensional construct. Moreover, many previous studies have relied on generic quality-of-life instruments that may not adequately capture the disease-specific reproductive concerns experienced by women with SLE [9–11]. Furthermore, reproductive health in women with SLE has rarely been conceptualized within an integrated framework encompassing physical, psychological, sexual, social, and spiritual dimensions simultaneously, despite increasing emphasis on patient-centered care in rheumatology and women's health research[12]

Importantly, the relationship between disease-related characteristics—including disease duration, disease activity, organ involvement, and treatment exposure—and multidimensional reproductive health outcomes remains insufficiently characterized. In particular, the impact of graded disease activity, as measured by standardized clinical indices, on distinct reproductive health domains has rarely been systematically examined. This issue is clinically relevant because disease activity may influence symptom burden, treatment intensity, emotional well-being, interpersonal relationships, and future reproductive decision-making, all of which can shape women's reproductive health experiences[13]

Therefore, the present study aimed to investigate the association between SLE disease characteristics—particularly disease activity grading—and multidimensional reproductive health outcomes in women of reproductive age. Reproductive health was assessed across physical, psychological, social, sexual, and spiritual domains using a validated disease-specific instrument aligned with the WHO reproductive health framework.

Materials and Methods

Study Design and Ethical Considerations

This cross-sectional descriptive–analytical study was conducted between January 28, 2023, and March 20, 2024. Ethical approval was obtained from the Research and Technology Vice Chancellor of Tehran University of Medical Sciences (Approval No: XXXX). The study was conducted in accordance with the Declaration of Helsinki. Reporting followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines[14].

Participants and Setting

The study population consisted of married (including divorced but sexually active) women aged 15–49 years with a confirmed diagnosis of systemic lupus erythematosus (SLE). Diagnosis was established by a rheumatology specialist according to the American College of Rheumatology (ACR) classification criteria [15] and confirmed through medical record review.

Participants were recruited from Shariati Hospital (a tertiary referral center) and the Lupus Association of Iran registry. From 930 eligible women identified in the electronic registry, 429 participants were selected using simple random sampling via an online randomization tool (www.random.org).

Inclusion Criteria

Study participants included according to confirmed diagnosis of SLE at least 12 months prior to enrollment, Age between 15 and 49 years, Not pregnant at the time of the study and not within 12 months postpartum, Ability to

communicate in Persian or Turkish, and Ability to provide informed consent and complete questionnaires**.**

Exclusion Criteria

Criteria to excluded participants were Physician-advised sexual abstinence, Current hospitalization, Severe mobility restrictions, Major physical or psychological disorders unrelated to SLE, and Active malignancy or severe unstable chronic disease.

Participants with controlled chronic conditions (e.g., hypertension, diabetes, thyroid disorders) were included, as these conditions are common in SLE and relevant to reproductive health evaluation.

Disease Activity Assessment

Disease activity was assessed using the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). The SLEDAI evaluates disease manifestations over the previous 10 days across 24 clinical and laboratory descriptors grouped into nine organ systems. Items are scored dichotomously (present/absent), generating a global disease activity score. Disease activity was categorized as: 0: No activity (remission), 1–5: Mild, 6–10: Moderate, and11–19: Severe[16].

Data Collection Instruments

Two instruments were used:

*Demographic and Clinical Questionnaire:*This form included age, education level, employment status, disease duration, medication use, organ involvement, and comorbidities.

Reproductive Health Assessment of Systemic Lupus Erythematosus (RHASLE): Reproductive health was assessed using the RHASLE instrument, a culturally developed and psychometrically validated tool for Iranian women with SLE. The questionnaire contains 27 items across five dimensions: Physical–psychological disorder, Feeling of relaxation, Sexual satisfaction, High-risk pregnancy, and Spirituality. Items are rated on a five-point Likert scale. Sixteen items (1–8, 11, 13–15, 17–19, and 24) were reverse-scored. After applying weighted scoring, total scores ranged from 99.92 to 499.6, with higher scores indicating better reproductive health. The instrument previously demonstrated strong psychometric properties, including high construct validity (validity coefficient = 0.926) and internal consistency reliability (Cronbach's α = 0.919) [17].

Sample Size Calculation

Sample size was calculated for multivariable linear regression analysis using G*Power software (version 3.1). Based on previous findings reporting [17] a mean reproductive health score of 232.14 (SD = 47.49), the calculation assumed a small-to-moderate effect size ($f^2 = 0.04$), six predictors, $\alpha = 0.01$, and statistical power $(1-\beta) = 0.90$. The minimum required sample size was estimated at 390 participants. To account for potential attrition and incomplete data, 10% was added, resulting in a target sample size of 429 participants.

Data Collection Procedure

Eligible participants were contacted by telephone, screened for inclusion criteria, and invited to participate. After providing informed consent, participants completed questionnaires either online or via structured telephone interview.

Two research team members independently reviewed the collected data for completeness and accuracy. Of the 429 collected questionnaires, 58 contained missing responses. Participants were contacted to complete missing data when possible. Questionnaires with more than 20% missing data were excluded (n = 29), resulting in 400 complete cases included in the final analysis.

Statistical Analysis

Upon reviewing the online questionnaires, it was discovered that 58 questionnaires had missing information. The researcher tried to fill in the missing information by contacting the women via phone using special codes, but ultimately, 29 questionnaires were excluded due to missing data exceeding 20%. Therefore, 400 questionnaires were included in the analysis.

Data were analyzed using SPSS version 26 (IBM Corp., Armonk, NY, USA). Descriptive statistics (mean, standard deviation, frequency, and percentage) were used to summarize demographic, clinical, and reproductive health variables. Normality of continuous variables was assessed using skewness and kurtosis statistics, histogram inspection, and the Kolmogorov–Smirnov test. Group comparisons of reproductive health scores across disease characteristics (e.g., disease activity category, disease duration, organ involvement, and comorbidities) were conducted using independent-samples t-tests or one-way ANOVA, as appropriate.

Multivariable Analysis

Associations between disease characteristics and reproductive health domains were examined using multivariable linear regression models. Clinically relevant covariates were selected a priori based on literature and theoretical relevance, including: Age, Disease duration, Education level, Employment status, Medication use, Disease activity (SLEDAI category). No automated stepwise procedures were employed to avoid model overfitting. Before regression modeling, assumptions were evaluated: Multicollinearity using variance inflation factors (VIF <5 considered acceptable), Independence of errors using the Durbin–Watson statistic, Normality of residuals via histogram and normal probability plots, Homoscedasticity using standardized residual scatterplots. Regression coefficients (B), standardized coefficients (β), 95% confidence intervals, and p-values are reported. Adjusted R^2 values were used to describe explanatory strength. Given the cross-sectional design, findings are interpreted as associations rather than causal or predictive effects. A two-sided p-value <0.05 was considered statistically significant.

Ethics approval

The current investigation received approval from the Ethics Committee of the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences on 28, Jan, 2023, under the code IR.TUMS.SHARIATI.REC.1401.024.

Results

Participant Characteristics

Of the 429 recruited participants, 400 complete questionnaires were included in the final analysis (response completeness rate: 93.2%). The mean age of participants was 35.85 years (SD = 5.78), and the mean body mass index (BMI) was 25.58 kg/m² (SD = 4.91). The mean age at SLE onset was 23.23 years (SD = 9.45). Nearly half of the participants (43.5%, n = 174) had lived with SLE for more than 10 years. Regarding disease activity, 28.75% (n = 115) had no active disease (remission), while 71.25% (n = 285) had active disease. Among those with active

disease, 58% (n = 205) were classified as having mild-to-moderate activity, and the remainder had severe activity. Slightly more than half of the women (51.5%) reported no comorbid conditions. Bivariate analyses using one-way ANOVA demonstrated statistically significant differences in total reproductive health scores across disease activity categories ($p < 0.001$). Education level ($p = 0.046$), marital status ($p = 0.027$), and presence of comorbid conditions ($p = 0.040$) were also significantly associated with overall reproductive health scores (Table 1).

Table 1
, Characteristics of women's SLE and correlation with RHASLE

Variable			SLE		F, r/ P Value
			N (%)/ Mean ± SD	Min-Max	
Age			35.85 ± 5.78	22–46	-0.105 [a] / 0.285
BMI			25.58 ± 4.91	14–63.67	0.014 [a] / 0.885
Education Level		Illiterate	5 (1.25)		2.46[b] / 0.046 df: 5
		Less than diploma	33 (8.25)		
		Diploma	33 (8.25)		
		Academic	73 (18.25)		
		College	256 (64)		
Marital and life status		With a partner	358 (89.5)		3.94[b] / 0.021 df: 5
		Without a partner	28 (7)		
		Divorced	14 (3.5)		
Onset age of SLE			23.23 (9.45)	2–50	0.010 [a] / 0.872
SLE duration		Less than 1 year	7 (1.75)		0.18 [b] / 0.623 df: 2
		1–5 years	101 (25.25)		
		6–10 years	118 (29.5)		
		More than 10 years	174 (43.5)		
SLE Grade (SLEDAI Score)	1	Silent	115 (28.75)		14.22 [b] / <0.001 df: 2
	2	Active, Mild or moderate	232 (58)		
	3	Active, Severe	53 (13.25)		
Other Disease with SLE		None	205 (51.25)		2.39[b] / 0.04 df: 5
		Hypertension	53 (13.25)		
		Diabetes	9 (2.25)		
		Heart disease	7 (1.75)		
		Kidney disease	56 (14)		
		Others(Brain Disease, Stroke,…)	70 (17.5)		
			400 (100)		

[a] Pearson; [b] One way ANOVA

Reproductive Health Scores

The mean total RHASLE score was 368.08 (SD = 52.58; range: 184.2–486.4), indicating a moderate level of reproductive health within the study population. The distribution of scores demonstrated acceptable skewness and kurtosis values, supporting approximate normality.

Across RHASLE domains, the highest mean score was observed in the Spirituality domain (128.8 ± 23.3), while the lowest mean score was reported in the High-Risk Pregnancy domain (35.4 ± 9.5). Mean scores with corresponding 95% confidence intervals are presented in Table 2.

Table 2
Reproductive Health domains situation in women with SLE

Domains	**mean (SD)**	**Min - Max**	**Skewness**	**Kurtosis**	**CI [c] (Lower - Upper)**
Physical-Psychological Disorder (PPD)	110.47(30.62)	43.32-168.05	-0.17	-0.84	6.68–12.66
Relaxing feeling (RLx)	46.52 (8.16)	13.3–66.50	0.55-	0.80	5.82–7.42
Spirituality (Spr)	128.81 (23.25)	28.83–144.15	1.72-	2.69	40.05–44.60
High Risk Pregnancies (HRP)	35.43 (9.54)	9.99–49.95	-0.76	-0.41	4.55–6.41
Sexual Satisfaction (SxS)	46.83 (14.33)	14.19–70.95	0.46	-0.39	2.87–5.67
Total score of RHASLE	368.08 (52.58)	184.23–486.4	0.36	-0.25	63.25–73.52

PPD = Physical–Psychological Disorder; RLx = Relaxing Feeling; Spr = Spirituality; HRP = High–Risk Pregnancy; SxS = Sexual Satisfaction; RHASLE = Reproductive Health Assessment of Systemic Lupus Erythematosus; SD = Standard Deviation; Min–Max = Minimum–Maximum value; CI = 95% Confidence Interval

Table 3
, Multiple linear regression of SLE grad and their relationship with RHASLE domains in women with SLE

variables		Unstandardized Coefficients		Standardized Coefficients	R* Square	P-value	t	95.0% Confidence Interval	
		B	Std. Error	Beta				Lower Bound	Upper Bound
PPD	Severe disease activity (ref = mild/moderate)	-18.81	6.88	-0.403	0.48	0.007	-2.73	-32.40	-5.23
	Silent disease activity (ref = mild/moderate)	13.79	4.94	0.207		0.006	2.79	4.04	23.55
SxS	Severe disease activity	-7.07	3.31	-0.263	0.236	0.034	-2.13	-13.61	-0.53
RHASLE Total	Severe disease activity	-37.61	13.45	-0.459	0.495	0.006	-2.79	-64.17	-11.05
	Silent disease activity	22.14	9.66	0.272		0.023	2.29	3.06	41.22

* Each dependent variable (PPD, Spr, HRP, Total RHASLE) was entered into separate models by using the enter method, so it was reported R^2 for each model separately. Other domains of RHASLE (Rlx, Sp, HRP) didn't have significant models.

*Each model adjusted for age, disease duration, education, employment, medication use, and presence of comorbid diseases with lupus. Disease activity was categorized as silent, mild/moderate (reference), or severe using SLEDAI. Regression coefficients (B), standardized coefficients (β), and adjusted R^2 are reported.

*PPD = Physical–Psychological Disorder; SxS = Sexual Satisfaction; RHASLE = Reproductive Health Assessment of Systemic Lupus Erythematosus

B = Unstandardized Regression Coefficient; β = Standardized Regression Coefficient; Std. Error = Standard Error of the Regression Coefficient

CI = Confidence Interval; Adjusted R^2 = Proportion of variance in the dependent variable explained by the model, adjusted for number of predictors.

Multivariable Linear Regression Analysis

Multivariable linear regression models were conducted to examine associations between disease activity and reproductive health outcomes, adjusting for age, disease duration, education, employment status, and medication use.

Prior to modeling, regression assumptions were evaluated. The Durbin–Watson statistic was 1.68, indicating independence of errors. Variance inflation factor (VIF) values were below 2.5 for all predictors, suggesting no evidence of multicollinearity. Residual plots and normal probability plots supported assumptions of normality and homoscedasticity. Disease activity was entered into the models as a categorical variable, with mild-to-moderate activity serving as the reference group.

Associations with Severe Disease Activity

Compared with mild-to-moderate disease activity, severe disease activity was significantly associated with: Lower Physical–Psychological Disorder scores (β = −0.403, p = 0.007); Lower Sexual Satisfaction scores (β = −0.263, p = 0.034); Lower Total RHASLE scores (β = −0.459, p = 0.006). These standardized coefficients indicate that severe disease activity is moderately and negatively associated with overall reproductive health, particularly in the physical–psychological and sexual satisfaction domains.

Associations with Silent Disease Activity

Compared with mild-to-moderate disease activity, silent disease activity (remission) was significantly associated with: Higher Physical–Psychological Disorder scores (β = 0.207, p = 0.006), and Higher Total RHASLE scores (β = 0.272, p = 0.023). These findings indicate that remission status is positively associated with better overall reproductive health outcomes.

Model Fit

The regression models explained a moderate proportion of variance in reproductive health outcomes, with adjusted R^2 values ranging from 0.28 to 0.49 across domains. The highest explanatory power was observed for the total RHASLE score model (adjusted R^2 = 0.49).

Overall, higher disease activity in SLE was significantly associated with lower reproductive health scores, particularly in the physical–psychological and sexual satisfaction domains. Conversely, remission status was associated with better reproductive health outcomes. Given the cross-sectional design, these findings reflect associations rather than causal relationships.

Discussion

This study examined the association between disease activity and multidimensional reproductive health in women with systemic lupus erythematosus (SLE) using a disease-specific, culturally validated instrument (RHASLE). The principal finding was that higher disease activity, particularly severe SLE, was independently associated with lower reproductive health scores in the physical–psychological well-being and sexual satisfaction domains, as well as in overall reproductive health. Conversely, remission or silent disease activity was associated with more favorable reproductive health outcomes. These findings suggest that disease activity is closely linked to women's broader reproductive health experiences beyond conventional clinical outcomes.

Importantly, the High-Risk Pregnancy domain of RHASLE reflects women's perceived pregnancy-related concerns and experiences rather than objectively verified obstetric complications. This distinction is important because the present study did not directly assess clinical pregnancy outcomes. Instead, it evaluated women's perceptions of reproductive risk within the context of living with SLE, which is consistent with the WHO definition of reproductive health as encompassing physical, mental, and social well-being rather than merely the absence of disease[8]

Our findings are consistent with previous studies demonstrating that disease activity plays a significant role in sexual and reproductive health among women with SLE. Behboudi et al. [18] reported that higher disease activity, along with depressive symptoms and age, was associated with impaired sexual functioning in women with lupus. Similarly, Kothari et al. [19] and Andreoli et al. [20] emphasized that active disease and treatment-related factors contribute substantially to adverse pregnancy outcomes in SLE. While many previous investigations have primarily focused on obstetric complications and fetal outcomes [19–21], the present study expands this perspective by

evaluating reproductive health as a multidimensional construct incorporating psychological well-being, sexual satisfaction, social concerns, and spirituality.

By framing reproductive health within the WHO multidimensional model, the present study moves beyond traditional outcome-oriented approaches focused solely on fertility or obstetric complications. This framework highlights how disease activity may simultaneously influence psychological well-being, sexual relationships, perceived reproductive security, and broader social functioning in women with SLE. Such a multidimensional perspective may provide a more patient-centered understanding of reproductive health in chronic autoimmune disease [13]

Chronic autoimmune diseases such as SLE affect not only organ systems but also interpersonal relationships, body image, sexual functioning, family planning decisions, and emotional well-being. By applying a validated disease-specific instrument and adjusting for relevant sociodemographic and clinical covariates in multivariable analyses, our findings provide evidence that disease activity is associated with several reproductive health domains simultaneously. The moderate adjusted R^2 values observed indicate that although disease activity is an important determinant, reproductive health outcomes are multifactorial and likely influenced by additional psychosocial, cultural, and interpersonal factors.

Differences between our findings and those reported in other populations may partly reflect sociocultural context. In Iran, sociocultural expectations regarding fertility, marital stability, and gender roles may intensify the perceived burden of reproductive challenges among women living with chronic illness. Concerns related to fertility, pregnancy risk, marital relationships, and social expectations may therefore become more closely intertwined with disease experience than in some Western populations [22]. In addition, cultural norms surrounding discussions of sexuality may influence self-reporting patterns and perceptions of sexual satisfaction and psychological distress.

From a clinical perspective, these findings reinforce the importance of integrating reproductive and sexual health assessment into routine rheumatology care for women with SLE. Although disease activity monitoring remains fundamental for preventing organ damage and improving long-term prognosis, comprehensive care should also include structured evaluation of sexual functioning, psychological well-being, reproductive concerns, and counseling needs. Multidisciplinary approaches involving rheumatologists, gynecologists, reproductive health specialists, and mental health professionals may help address these complex and interrelated needs more effectively.

Clinical implications

The findings suggest that disease activity in systemic lupus erythematosus (SLE) is associated with clinically meaningful differences across multiple domains of reproductive health, particularly physical–psychological well-being and sexual satisfaction. Routine assessment of reproductive and sexual health may therefore be beneficial as part of comprehensive SLE management, especially among women with moderate to severe disease activity.

Use of structured disease-specific instruments such as RHASLE may facilitate earlier identification of reproductive and psychosocial concerns that are frequently underrecognized in routine clinical care. Furthermore, optimizing disease control may contribute not only to reduced disease burden but also to improved patient-centered reproductive health outcomes.

These findings support multidisciplinary models of care that encourage collaboration among rheumatologists, gynecologists, reproductive health specialists, and mental health professionals in addressing the broader reproductive health needs of women with SLE.

Strengths and limitations of this study

This study has several strengths. It included a relatively large sample of women with confirmed SLE and used a disease-specific, culturally validated reproductive health instrument aligned with the WHO framework. In addition, adjustment for multiple sociodemographic and clinical covariates strengthened the robustness of the findings and allowed evaluation of multidimensional reproductive health domains simultaneously.

However, several limitations should be considered. First, due to the cross-sectional design, causal relationships between disease activity and reproductive health outcomes cannot be established. Second, data were collected using self-report measures, which may be subject to recall bias and social desirability bias, particularly in culturally sensitive domains such as sexuality and reproductive concerns. Third, participants were recruited from a single national context, which may limit generalizability to other cultural settings. Finally, only women were included because the RHASLE instrument was specifically designed to assess women's reproductive health in SLE.

Conclusions

In this cross-sectional study, higher disease activity in women with systemic lupus erythematosus was independently associated with poorer reproductive health, particularly in physical–psychological well-being and sexual satisfaction domains. Remission status was associated with more favorable outcomes. These findings underscore the importance of incorporating comprehensive reproductive and sexual health evaluation into routine lupus management, recognizing that disease control may be closely linked to women's broader reproductive experiences. A holistic, culturally informed approach to care may help improve quality of life for women living with SLE.

Declarations

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None

Author Contribution

E.R.: Conceptualization, Investigation, Project administration, Validation, Visualization, Writing – original draft; Writing – review & editing; A.Z.: Formal analysis, Writing proposal and investigation; Z.B.M.: Conceptualization, Methodology, Supervision, Writing – review & editing; S.T.F: Investigation, Project administration; Writing – original draft. All authors reviewed the manuscript.

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Data Availability

The datasets generated and/or analyzed during the current study are not publicly available due to ethical restrictions but are available from the corresponding author on reasonable requests.

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