Large population-based assessment of SARS-CoV-2 teratogenicity by profiling congenital anomalies during COVID-19 pandemic

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Abstract

Objective: This study examined population-level trends in congenital anomalies before and during the coronavirus disease-19 (COVID-19) pandemic in India, which experienced one of the most severe COVID-19 outbreaks with multiple devastating waves.

Material and Methods: We conducted a retrospective analysis of prospectively collected data from the Antenatal Detection of Congenital Anomalies registry between pre-pandemic (January 2018-May 2020) and pandemic (June 2020-December 2022). Time series analysis examined temporal trends and seasonal patterns.

Results: Among 175,749 prenatal scans, 2.895 congenital anomalies were detected (overall rate 16.5 per 1,000 scans). Detection rates were similar pre-pandemic (14.8 per 1,000 scans, n=1.370) and during the pandemic (18.3 per 1.000 scans, n=1.525; p=0.096). The distribution of anomalies by organ system remained consistent, with head/neck and genitourinary anomalies predominating (19-23% and 14-22% annually, respectively). A persistent seasonal pattern was observed, with peaks in the fourth quarter annually (mean November: 62.7 cases) and troughs at the beginning of each year (mean January: 36.8 cases). The Seasonal Autoregressive Integrated Moving Average model accurately predicted 2023 trends confirming the stability of the epidemiologic process.

Conclusion: Our large-scale study provides compelling evidence that the COVID-19 pandemic was not associated with a change in the rate or pattern of congenital anomalies at the population level. The discovery of a robust seasonal variation in anomaly detection represents a significant finding that demands detailed delineation to inform preventive strategies. [J Turk Ger Gynecol Assoc. 2026; 27(2): 76-83]

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Introduction

Congenital anomalies affect approximately 3-6% of births globally and remain a leading cause of infant mortality (1,2). Structural malformations are caused by disruptions during organogenesis in the first trimester of pregnancy (weeks 1-13 of gestation) (3). Understanding the factors that influence these disruptions is important to inform preventive strategies and prenatal counselling.

On March 11, 2020, the World Health Organization declared the coronavirus disease-19 (COVID-19) pandemic a public health emergency. It severely disrupted healthcare systems worldwide. Concerns were raised regarding the potential teratogenic effects of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (4,5). Evidence emerged that linked maternal SARS-CoV-2 infection to adverse pregnancy outcomes associated with placental dysfunction, fetal distress, preterm birth, low birth weight, and increased neonatal intensive care unit admissions (6). Multiple mechanisms were proposed for potential teratogenic effects, including direct viral infection by vertical transmission, use of antivirals and corticosteroids or alternate medicine in the mother, vaccination, and indirect factors, such as disrupted prenatal care for chronic conditions (diabetes, hypertension), maternal stress, and nutritional changes during the pandemic period (7-9).

Since 2020, studies examining the association between COVID-19 and congenital anomalies have yielded inconsistent results.

India experienced one of the world's largest COVID-19 outbreaks, accounting for approximately one-fifth of global cases during the pandemic period (10). The large population, substantial disease burden during multiple pandemic waves, and genetic diversity provide a unique opportunity to examine population-level trends in congenital anomalies. Furthermore, the endogamous structure of many Indian populations may amplify detection of recessive genetic conditions, potentially making this population particularly informative for studying any systematic changes in anomaly patterns.

The aim of the present study was to investigate whether the COVID-19 pandemic period was associated with changes in the rates, patterns, or temporal trends of structural congenital anomalies detected during routine prenatal screening in Tamil Nadu, South India. We employed time series analysis to characterize baseline patterns and pandemic-era trends, providing population-level evidence in real-world settings to guide clinical practice.

Material and Methods

Study design and setting

This retrospective cohort study analyzed prospectively collected data from a large tertiary care maternity center in Tamil Nadu, South India. This study was approved by the Ethics Committee of Christian Medical College (approval number: ECR/326/INST/TN/2013/RR-2019, date: 19.05.2023), and the requirement for individual informed consent was waived given the use of de-identified registry data.

Data source

Data were obtained from the Antenatal Detection of Congenital Anomalies (ADAC) registry, a prospectively maintained institutional database. The registry systematically records all structural anomalies detected during routine prenatal ultrasound examinations. All pregnant women receiving prenatal care at our institution undergo standardized ultrasound screening, including a first trimester scan (11-14 weeks gestation) and a second trimester anomaly scan (18-24 weeks gestation; comprehensive fetal anatomical survey following International Society of Ultrasound in Obstetrics and Gynecology guidelines) (11,12). All scans were performed by certified sonographers, using standardized protocols and equipment. Detected anomalies were reviewed and confirmed by maternal-fetal medicine specialists. Anomalies were classified according to the International Classification of Diseases, 10th revision coding system and categorized by primary organ system affected.

Study periods and exposure definition

The study period spanned 60 months from January 2018 through December 2022. Based on the WHO pandemic declaration (March 11, 2020) and the emergence of the first confirmed COVID-19 case in Tamil Nadu on March 7, 2020, we defined study periods as follows: pre-pandemic period: January 2018 through May 2020 (29 months) and pandemic period: June 2020 through December 2022 (31 months). The June 2020 start date for the pandemic period accounts for the approximate 3-month lag between potential first-trimester SARS-CoV-2 exposure (following pandemic onset in March 2020) and detection at the routine 18-24 week anomaly scan.

Statistical analysis

Categorical variables are presented as frequencies and percentages, continuous variables as means with standard deviations (SDs) or medians with interquartile ranges, as appropriate. The chi-square test was used to compare anomaly detection rates between periods. Two-sided p-values <0.05 were considered statistically significant.

Time series analysis

Time series decomposition was performed to examine trend, seasonal, and irregular components. The augmented Dickey-Fuller test assessed data stationarity (test statistic -4.86, $p<0.001$, indicating stationarity). Given the pronounced seasonal

pattern in the data, we employed Seasonal Autoregressive Integrated Moving Average (SARIMA) modeling. The general $SARIMA_{(p,d,q)}(P,D,Q)_s$ model structure includes p: order of non-seasonal autoregressive component, d: order of non-seasonal differencing, q: order of non-seasonal moving average component, P: order of seasonal autoregressive component, D: order of seasonal differencing, Q: order of seasonal moving average component, s: seasonal period (12 months). Model selection was based on minimization of the Akaike Information Criterion and Bayesian Information Criterion, along with examination of residual autocorrelation function and partial autocorrelation function plots. The optimal model, $SARIMA(0,0,0)(0,1,1)_{12}$, was validated using the Ljung-Box test for residual autocorrelation. All statistical analyses were performed using R version 4.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Study population and scan volume

During the 60-month study period, 175,749 prenatal ultrasound scans were performed and recorded in the ADAC registry. The pre-pandemic period (January 2018-May 2020) included 92,364 scans, while the pandemic period (June 2020-December 2022) included 83,385 scans.

Anomaly detection rates

A total of 2,895 structural congenital anomalies were identified during the study period, yielding an overall detection rate of 16.5 per 1,000 scans [95% confidence interval (CI): 15.9-17.1]. In the pre-pandemic period, 1,370 anomalies were detected among 92,364 scans [rate: 14.8 per 1,000 scans (95% CI: 14.1-15.6)]. In the pandemic period 1,525 anomalies were detected among 83,385 scans [rate: 18.3 per 1,000 scans (95% CI: 17.4-19.2)]. The difference in detection rates between periods was not statistically significant ($p=0.096$).

Distribution by organ system

The distribution of congenital anomalies by primary organ system affected remained remarkably consistent across both periods (Figure 1). The most frequently detected categories were head and neck anomalies (19-23% annually; including neural tube defects, craniofacial malformations, and brain anomalies) and genitourinary anomalies (14-22% annually including renal agenesis, hydronephrosis, and urinary tract malformations). Multiple system anomalies were 15-20% annually. No significant shift in the proportional distribution of anomaly types was observed between pre-pandemic and pandemic periods ($p=0.342$).

Temporal trends and seasonality

Time series decomposition revealed a striking and consistent seasonal pattern throughout the entire study period, persisting across both pre-pandemic and pandemic periods (Figure 2). Monthly anomaly detection showed peak detection in the fourth quarter (October-December) every year (October: mean 56.1 cases (SD: 7.8, range 45-69); November: mean 62.7 cases (SD: 8.9, range 48-78); December: mean 58.4 cases (SD: 9.2, range 42-case). A trough in detection was seen in the first quarter (January-March) of every year [January: mean 36.8 cases (SD: 5.6, range 28-47]; February: mean 38.2 cases (SD: 4.9, range 31-48); March: mean 41.5 cases [SD: 6.2, range 33-52)]. Intermediate rates occurred in the remaining months, April-September (mean range: 45.3-52.8 cases). July showed the highest variability (SD: 12.8). The coefficient of seasonal variation was 28.4%, indicating substantial periodic fluctuation.

SARIMA model and forecasting

The Augmented Dickey-Fuller test was performed to assess data stationarity with a test statistic of -4.86 ($p<0.001$). The optimal SARIMA model was used to predict anomalies for each month in the post-pandemic period, including 2023. The forecast demonstrated a continuation of the existing trend with seasonal patterns, accompanied by expanding CIs, reflecting appropriate increased uncertainty in long-term predictions (Figure 3). The actual and predicted values for the year 2023 are listed in Table 1. The actual values were within the upper and lower proximity limits for each month, respectively. In general, the predicted values were comparable to the actual values, indicating that the model could capture the underlying patterns in the data.

Discussion

The Indian population is highly endogamous in nature, characterized by sympatric isolation patterns which provides a unique and powerful “real-world” setting to investigate teratogenicity. This genetic structure can amplify the detection of subtle shifts in anomaly rates or the emergence of specific malformation patterns, making this population particularly sensitive for identifying new environmental insults, such as a potential viral teratogen.

This large registry-based study of 175,749 prenatal scans over five years found no significant change in the rate or pattern of structural congenital anomalies detected during the COVID-19 pandemic period compared to the pre-pandemic baseline. Although India faced one of the most severe COVID-19 outbreaks, marked by multiple waves impacting millions, the anomaly detection rate remained consistently stable at approximately 15-18 per 1,000 scans throughout the study period. Further, the distribution of anomalies by organ system remained

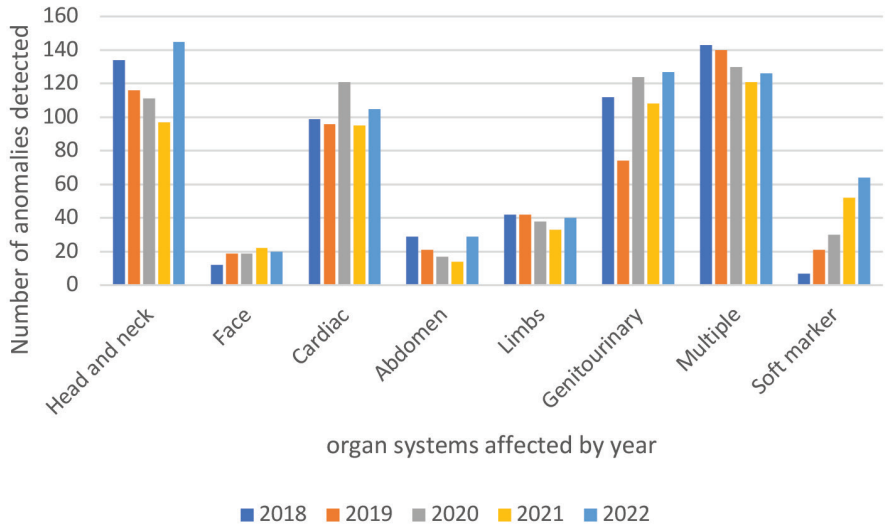

Figure 1. Distribution of detected anomalies by organ system from 2018 to 2022. The bar chart shows the number of anomalies detected across different organ systems. Each color represents a different year (2018–2022), allowing comparison of temporal trends in anomaly detection across organ systems

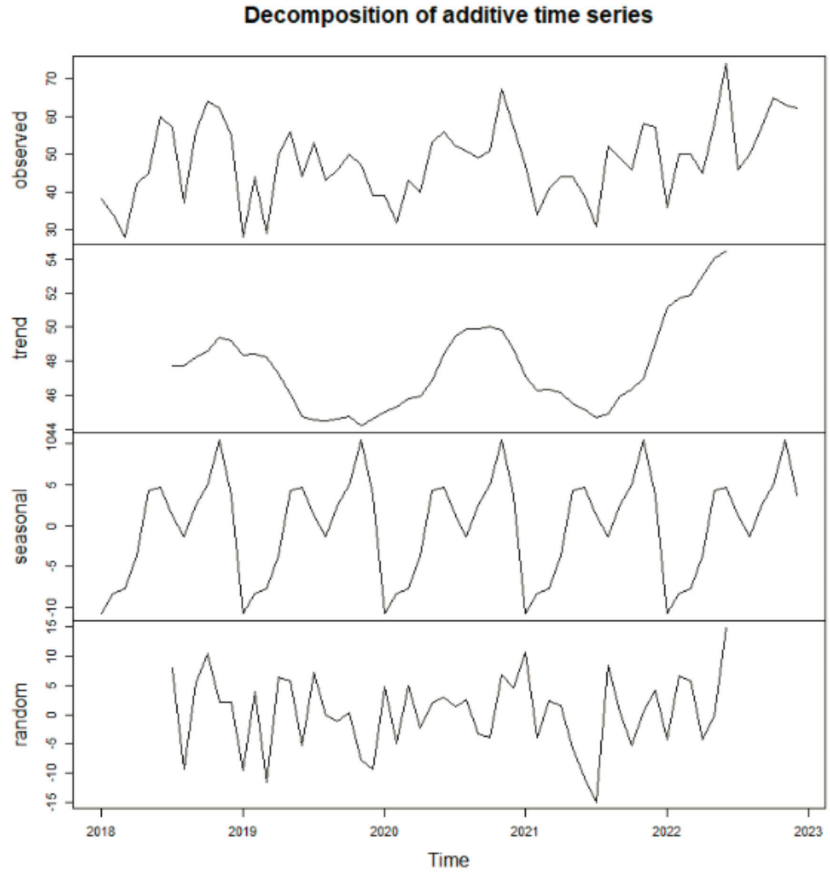

Figure 2. Additive time series decomposition of total anomalies from 2018–2022. The top panel shows the observed time series of total anomalies. The second panel represents the trend component, indicating the long-term progression of anomalies after removing seasonal effects. The third panel displays the seasonal component, reflecting repeating periodic patterns within each year. The bottom panel shows the random component, which represents irregular fluctuations remaining after removing both trend and seasonal effects

consistent, with head/neck and genitourinary malformations predominating. A marked and persistent seasonal pattern in anomaly detection with consistent fourth-quarter peaks and first-quarter troughs was noted, that was unaffected by the pandemic. Time series modelling accurately predicted future trends, suggesting stable underlying epidemiological patterns.

Our findings contribute to a growing but inconsistent body of literature examining the relationship between COVID-19 and congenital anomalies. An Iranian national birth registry analysis compared births during COVID-19 (Nov 2020-Feb 2021) with pre-pandemic births (Nov 2019-Feb 2020). Although the study period was only three months they found significantly increased incidence of congenital birth anomalies during the pandemic ($p<0.00001$), with particular increases in central nervous system ($p=0.04$) and genitourinary anomalies ($p=0.03$) (13). Auger et al. (14) performed an interrupted time series analysis of pre- and post-pandemic period and confirmed that the frequency of microcephaly increased during the late pandemic period. A study from China reported increased incidence of congenital heart disease during the pandemic, with incidence rates rising from 1.12% in 2020 to 5.46% in 2023 ($p<0.001$) (15). Among mothers with COVID-19 infection, 11 of 12 cardiac abnormalities occurred when infection happened before 8 weeks gestation. Studies from Iraq and Pakistan reported upward trends in neural tube defects during the pandemic (16,17). Another study reported association between SARS-CoV-2 infection during early weeks of gestation with situs inversus (18). Notably absent is the consistent pattern of specific anomalies that characterizes known teratogenic viral infections such as rubella, CMV, and Zika (19-22).

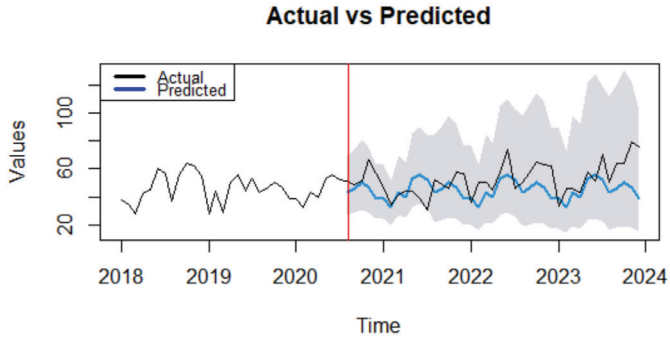

Figure 3. Observed and Seasonal Autoregressive Integrated Moving Average (SARIMA) predicted values of total anomalies. The black line represents the observed values from 2018 to 2023. The red vertical line indicates the start of the forecasting period (June 2020). The blue line shows the SARIMA model predictions for the post-training period. The grey shaded region represents the 95% prediction interval, illustrating the uncertainty associated with the forecast estimates. The widening of the interval over time reflects increasing uncertainty in longer term predictions

These findings must be considered alongside substantial evidence showing no meaningful associations. A prospective Nordic registry-based study included 343,066 liveborn singleton infants with pregnancies starting between March 2020 and February 2022 (23). Among 17,704 (5.2%) infants with major congenital anomalies, adjusted odds ratios for COVID-19 infection during the first trimester ranged from 0.84 (95% CI 0.51-1.40) for eye anomalies to 1.12 (0.68-1.84) for oro-facial clefts. The study concluded that COVID-19 infection and vaccination during the first trimester were not associated with risk of congenital anomalies. International Registry of Coronavirus Exposure in Pregnancy cohort study found that

Table 1. Actual and predicted values for 2023

Months	Actual value	Forecast value	Uncertainty limits	
			95 LCL	95 UCL
January 23	33	41	27.75	59.93
February 23	46	42	28.70	61.99
March 23	46	42	28.34	61.20
April 23	43	48	32.78	70.80
May 23	58	56	37.99	82.05
June 23	51	59	39.93	86.24
July 23	70	50	34.32	74.12
August 23	50	51	34.74	75.02
September 23	64	56	38.23	82.56
October 23	64	60	40.76	88.02
November 23	79	65	44.05	95.14
December 23	76	59	40.12	86.64

LCL: Lower confidence limit, UCL: Upper confidence limit

in pregnancies exposed to SARS-CoV-2 in the first trimester, the risk of any major congenital malformation did not differ significantly from an internal reference group with negative SARS-CoV-2 tests (24).

Several contextual factors warrant consideration in attributing to this disparity. Changes in healthcare access and prenatal screening practices during the pandemic may have influenced both detection and reporting of anomalies. The positive studies face challenges including healthcare disruption affecting case ascertainment, potential confounding from disease severity and treatment approaches, and in some cases, reliance on population-level rather than individual exposure data. The pandemic period saw increases in maternal stress, depression, metabolic dysregulation, delayed management of chronic conditions (diabetes, hypertension), and use of alternative medications (7-9,25). Changes in ultrasound protocols, operator experience (reassignment of personnel), or threshold for anomaly reporting may have occurred. Furthermore, women pregnant during the pandemic were reportedly older, more likely nulliparous, had higher BMI, and had higher rates of diabetes and hypertension which are all risk factors for congenital anomalies (7-9).

The consistent fourth-quarter peaks and first-quarter troughs in congenital anomaly detection in Tamil Nadu highlight a robust seasonal pattern that persisted across pre- and post-COVID-19 periods, suggesting structural, biological, or behavioral drivers, rather than SARS-CoV-2. In tropical regions such as Tamil Nadu, influenza and respiratory syncytial virus peak during July-August, coinciding with the monsoon season (26). Maternal infections during the periconceptional period may influence fetal development through direct teratogenic effects, immune-mediated mechanisms, or fever-related hyperthermia, all linked to anomalies such as neural tube and cardiac defects (27,28). The timing is compelling: infections in July-August affect conceptions in June-August, with anomaly scans at 18-22 weeks falling in October-December, matching observed peaks.

Nutritional seasonality also plays a role. Reduced availability of leafy greens during monsoon may lower folate intake, a critical factor in preventing neural tube defects (29). Cloud cover and reduced outdoor activity may impair vitamin D synthesis, while pre-harvest “hungry seasons” can exacerbate maternal undernutrition, affecting organogenesis (30). Environmental exposures during monsoon further compound risks. Increased gastrointestinal infections, pesticide exposure during agricultural cycles, and indoor air pollution from biomass fuels all pose potential teratogenic threats. Monsoon-related transport challenges can delay access to healthcare, while agricultural demands may postpone prenatal visits. Hospital workflow variations could theoretically affect detection rates, but the persistence of seasonal peaks despite pandemic disruptions argues against purely operational causes.

Prospective, multidisciplinary studies that integrate epidemiological surveillance with biological and environmental monitoring are required to test these hypotheses. Longitudinal cohort studies following women from the periconceptional period through pregnancy could capture viral exposure, nutritional status, and environmental factors in real time, while linking them to anomaly outcomes. Pre- and post-conceptual testing for folate, vitamin D, and markers of immune activation during febrile illness, would help clarify mechanistic pathways. Geospatial mapping of agricultural cycles, pesticide use, and healthcare access during monsoon seasons could provide contextual correlations, while qualitative studies on maternal health-seeking behavior would add sociocultural dimensions. Importantly, harmonizing anomaly detection protocols across centers and ensuring standardized timing of scans would minimize operational bias. Together, these approaches would unravel the biological, nutritional, environmental, and behavioral contributions to the observed seasonality, thereby strengthening causal inference and informing targeted public health interventions.

Study limitations

This study has several acknowledged limitations. We used population-level timing rather than individual-level SARS-CoV-2 infection or vaccination data, precluding assessment of infection timing relative to organogenesis, disease severity, or immunological responses, thus potentially masking individual-level associations. Registry-based ultrasound detection cannot capture subtle anomalies, postnatal diagnoses, early pregnancy losses, or pregnancy outcomes (terminations, stillbirths), and detection sensitivity may vary by operator experience or anomaly type. While adequately powered for overall rates, the study had limited ability to detect changes in specific rare anomalies or definitively distinguish biological from operational causes of seasonal variation. The available data did not permit sensitivity analyses. The 2.5-year pandemic follow-up may be insufficient to capture subtle or delayed effects. The single-center design limits generalizability to populations with different genetic backgrounds, healthcare systems, or pandemic experiences.

Further, the 10% decrease in scan volume during initial lockdowns (April-June 2020) suggests potential selection bias if healthcare access disruption differentially affected specific risk groups. We could not adjust for important confounders including maternal age, parity, BMI, chronic conditions (diabetes, hypertension), medications, socioeconomic factors, stress, or nutrition. Despite these limitations, strengths include the large sample size (175,749 scans),

a prospectively maintained pre-pandemic registry, standardized protocols, robust statistical methods including time series analysis, validation through accurate 2023 forecasting, and representation of a high COVID-19 burden setting maximizing potential to detect population-level effects

As COVID-19 transitions from pandemic to endemic status globally, these findings support continued reassurance during prenatal counselling. Furthermore, they highlight the critical importance of maintaining robust prenatal screening programs and registry systems during public health emergencies.

Conclusion

Over the five-year study period, prenatal ultrasound anomaly detection rates showed a modest increase during the pandemic compared to the pre-pandemic phase, though this difference was not statistically significant. The types of anomalies detected remained consistent, with head/neck and genitourinary anomalies being the most common, and no notable shifts in organ system distribution were observed. A clear seasonal pattern persisted throughout, with higher detection rates in the final quarter of each year and lower rates in the first quarter. Forecasting using a SARIMA model successfully captured these temporal trends, indicating stable anomaly surveillance and predictable seasonal variation despite external disruptions.

Ethics

Ethics Committee Approval: *This study was approved by the Ethics Committee of Christian Medical College (approval number: ECR/326/INST/TN/2013/RR-2019, date: 19.05.2023).*

Informed Consent: *The requirement for individual informed consent was waived given the use of de-identified registry data.*

Footnotes

Author Contributions: *Surgical and Medical Practices: S.J., M.M.B., P.R.N., M.K., S.S., B.J.R., J.F., Concept: S.J., J.F., Design: S.J, J.F., R.K., M.M.B., S.S., Data Collection or Processing: P.R.N., B.J.R., R.K., Analysis or Interpretation: S.J., J.F., M.M.B., Literature Search: S.J., M.M.B., P.R.N., Writing: S.J., J.F., R.K.*

Conflict of Interest: *No conflict of interest is declared by the authors.*

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