

Characterizing perinatal treatment patterns and outcomes in rheumatologic disease: A retrospective cohort study in a US health insurance claims database

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Background

Managing autoimmune conditions during pregnancy presents a complex challenge due to potential adverse outcomes in both the mother and fetus from the disease itself and available treatments. Studies to inform clinical management and therapeutic decision-making in these populations are often limited by small sample size. Moreover, there is limited understanding of real-world drug utilization in this population. We aimed to understand treatment patterns before, during, and after pregnancy among individuals affected by three autoimmune conditions: Rheumatoid Arthritis (RA), Systemic Lupus Erythematosus (SLE) and Sjogren's disease (SjD) using large US real-world databases.

Methods

We conducted a retrospective cohort study using data from 2000 to 2022 in four US insurance claims databases: Optum© De-Identified Clinformatics® Data Mart Database – Date of Death-(DOD) (Clinformatics) dataset and Merative MarketScan® Databases: Commercial Claims (CCAE), Multi-state Medicaid (MDCD), Pharmedics Plus (Pharmedics). Pregnant individuals aged 18-49 were identified using a hierarchical algorithm that leverages the presence and timing of prenatal healthcare encounters. RA, SLE, and SjD were defined by ≥ 2 diagnoses within a 365-day period and ≥ 1 diagnosis before the end of pregnancy. Condition-specific treatments were summarized at the class level and included corticosteroids, non-steroidal anti-inflammatory drugs, non-biologic disease modifying anti-rheumatic drugs (dMARDs), biologic dMARDs, and teratogens. The analysis examined dispensed treatments by condition in each class across three time periods: preconception (6 months before estimated start of pregnancy), pregnancy (start of pregnancy until end of pregnancy), and postpartum (6 months after end of pregnancy). Continuation across time periods was defined as at least one prescription fill in the same class as a therapy prescribed in the previous time period; discontinuation was defined as the absence of a fill in the time period. To enable observation of treatment patterns, cohorts were limited to those with ≥ 6 months of continuous enrollment in the database before estimated pregnancy start through ≥ 6 months after estimated pregnancy end.

Results

For brevity, the results from CCAE, the largest available database, are presented. Among those with RA (n=7,029), SLE (n=6,996), and SjD (n=2,259), the proportions of patients receiving no treatment increased from preconception to pregnancy: 29.4% to 42.2%, 36.0% to 42.7%, and 43.1% to 51.0%, respectively. One third to one half of patients received any treatment throughout all time periods (46% in RA, 44% in SLE and 34% in SjD, Figure 1). The proportion of corticosteroid use in each time period varied by condition, with RA patients most likely to take them across all time periods, followed by those with SLE, and SjD (Table 1). Among the 33.6%, 29.8%, and 22.5% on corticosteroids in pregnancy, 35.3%, 38.7% and 50.0% had not taken them in preconception across RA, SLE, and SjD, respectively

(Table 2). The use of methotrexate, a conventional synthetic DMARD, also varied by condition and across preconception, pregnancy, and postpartum; from 8.7%, 2.9% and 9.9% for RA, 1.6%, 0.8%, 1.8% in SLE and 1.6%, 0.7% and 1.7% in SjD, respectively.

Figure 1. Percentage of patients treated during each time period combination in CCAE

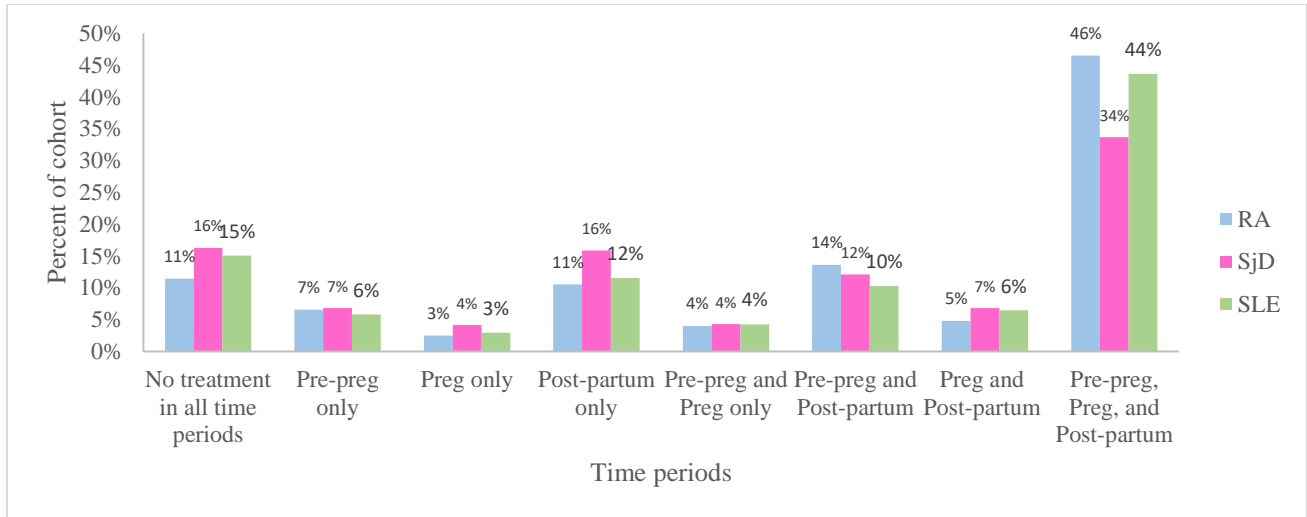


Table 1. Proportion of systemic corticosteroid use across conditions and time periods in CCAE

Condition	Total pregnancies	Preconception		Pregnancy		Postpartum	
		N	%	N	%	N	%
RA	7029	2784	39.6%	2365	33.6%	2828	40.2%
SjD	2259	598	26.5%	508	22.5%	568	25.1%
SLE	6996	2356	33.7%	2085	29.8%	2335	33.4%

Table 2. Proportions of women treated with corticosteroids in pregnancy period and proportion who did or did not continue from prior preconception period in CCAE across conditions.

Condition	Pregnancy exposures	Proportion who continue from preconception		Proportion of patients without use in preconception	
	N	N	%	N	%
RA	2365	1530	64.7%	835	35.3%
SjD	508	254	50.0%	254	50.0%
SLE	2085	1279	61.3%	806	38.7%

Conclusions

This study identified several thousand pregnancies across a 20-year period in the US. In patients affected by RA, SLE, and SjD, treatment patterns during the perinatal period were dynamic, with one third to one half using therapies before, during, and after pregnancy. Corticosteroids were most commonly used in pregnancy across all conditions. However most pregnant individuals received no treatments during pregnancy, Emphasizing the necessity for safe treatment options in pregnancy. Future research can elucidate treatment switching patterns as well as characterize disease severity underlying treatment utilization in the perinatal period.