

# Comparison of pregnancy characteristics and outcomes in women with systemic lupus erythematosus in two different German data sources: a nationwide pregnancy register and a claims data base

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EULAR 2025 POS1327

## INTRODUCTION

- Systemic lupus erythematosus (SLE) is a complex chronic autoimmune disease with female predominance and disease onset in reproductive age.
- Pregnancies in women with SLE are classified as high-risk since they are associated with more frequent maternal and fetal complications compared to the general population.
- Pregnant women are usually excluded from clinical trials, current knowledge largely relies on observational data. Differences in data sources may influence patient profiles and outcomes.

## AIM

To compare pregnancy characteristics and adverse pregnancy outcomes (APO) in women with SLE in two different German data sources: the pregnancy registry Rhekiss and claims data from the BARMER statutory health insurance.

## PATIENTS AND METHODS

- Data sources:** (I) **Pregnancy registry Rhekiss**, a nationwide, multicentre, web-based longitudinal cohort study, initiated in 2015 to investigate pregnancies in women with inflammatory rheumatic diseases. Women can either be enrolled if they are planning a pregnancy or if they are already pregnant prior to gestational week 20. (II) Nationwide **BARMER claims database** that covers 11 million insurants.
- Selection criteria:** Registry data – women with SLE and a singleton pregnancy reported between 2015 and 2023. Claims data – women aged 18-55 years with  $\geq 2$  outpatient or  $\geq 1$  inpatient diagnosis of SLE within 12 months in the years 2005-2023. Singleton pregnancies/deliveries were identified via ICD-10, procedure and operation codes.
- Data analysis:** Descriptive analysis to investigate maternal characteristics and APOs.

## RESULTS

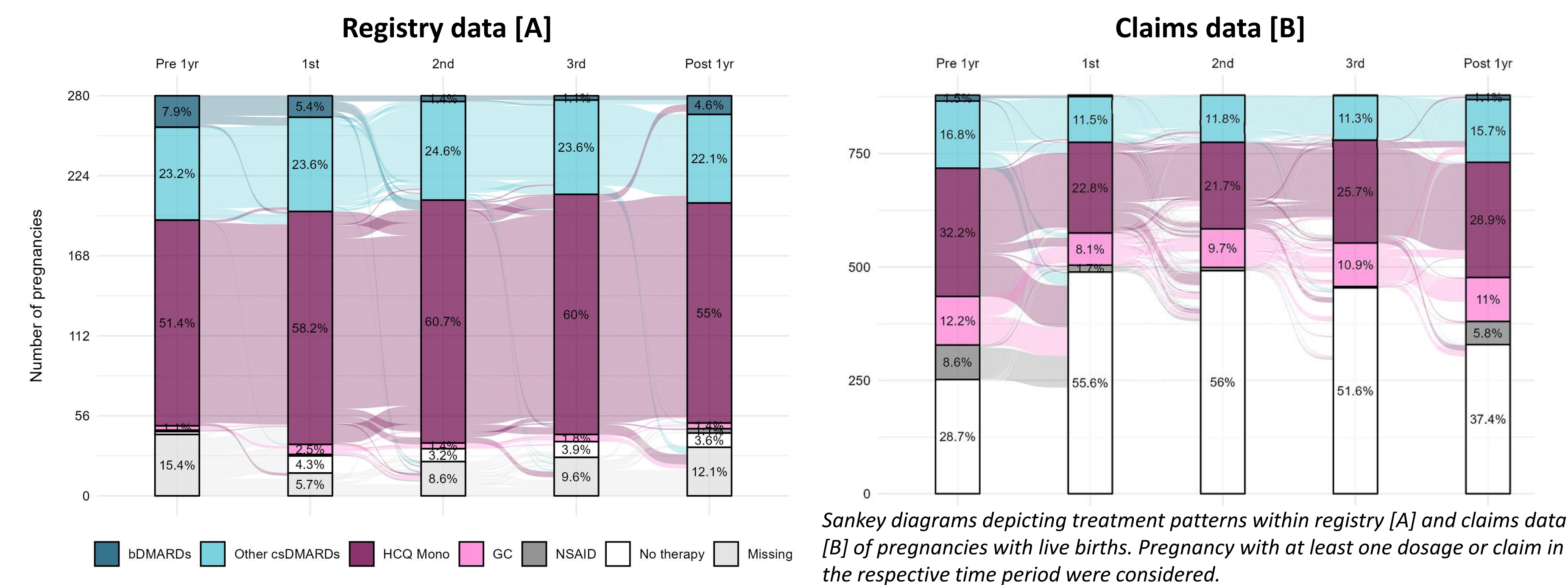
A total of 1.204 singleton pregnancies were available, n=325 from the registry and n=879 from the claims database (table).

	Registry data	Claims data
Number of pregnancies	325	879
Number of women	276	649
<b>Baseline characteristics</b>		
Maternal age, years	31.7 $\pm$ 4.2* (MIN: 20   MAX: 42)	33.3 $\pm$ 4.5 <sup>§</sup> (MIN: 21   MAX: 49)
Disease duration, years	8.2 $\pm$ 5.6*	5.3 $\pm$ 3.6 <sup>‡</sup>
Arterial hypertension	33 (13.6)*	132 (15.0) <sup>§</sup> [I10-I15] <sup>#</sup>
Autoimmune thyroiditis	33 (13.6)*	102 (11.6) <sup>§</sup> [E06.3] <sup>#</sup>
Glomerulonephritis	39 (16.1)*	67 (7.6) <sup>§</sup> [N08.5] <sup>#</sup>
Antiphospholipid syndrome	31 (12.8)*	102 (11.6) <sup>§</sup> [D68.6] <sup>#</sup>
Diabetes mellitus	5 (2.1)*	37 (4.2) <sup>§</sup> [E10-E14] <sup>#</sup>
<b>Complications during pregnancy</b>		
Arterial hypertension	13 (4.6)	21 (2.4) [O13] <sup>#</sup>
(Pre)Eclampsia or HELLP	8 (2.5)	82 (9.3) [O14-O15] <sup>#</sup>
Gestational diabetes	10 (3.2)	91 (10.4) [O24.4]
<b>Outcome of pregnancy</b>		
Miscarriage	17 (5.6)	14 (1.6)**
Termination	4 (1.3)	43 (4.9)
Stillbirth	1 (0.3)	5 (0.1)
Live birth	280 (92.7)	817 (93.5)
Spontaneous	139 (57.2)	565 (69)
thereof Caesarean section	97 (39.8)	239 (29)
thereof operative vaginal	8 (3.3)	18 (2.0)
thereof preterm delivery	42 (15.3)	107 (13.1)

\*At the time of conception. <sup>§</sup>In the year of pregnancy outcome. <sup>#</sup>ICD-10 Codes used in claims database. <sup>‡</sup>Starting from the date, diagnosis criteria were fulfilled. <sup>§</sup>In calendar year before conception. \*\*Includes ectopic pregnancy.

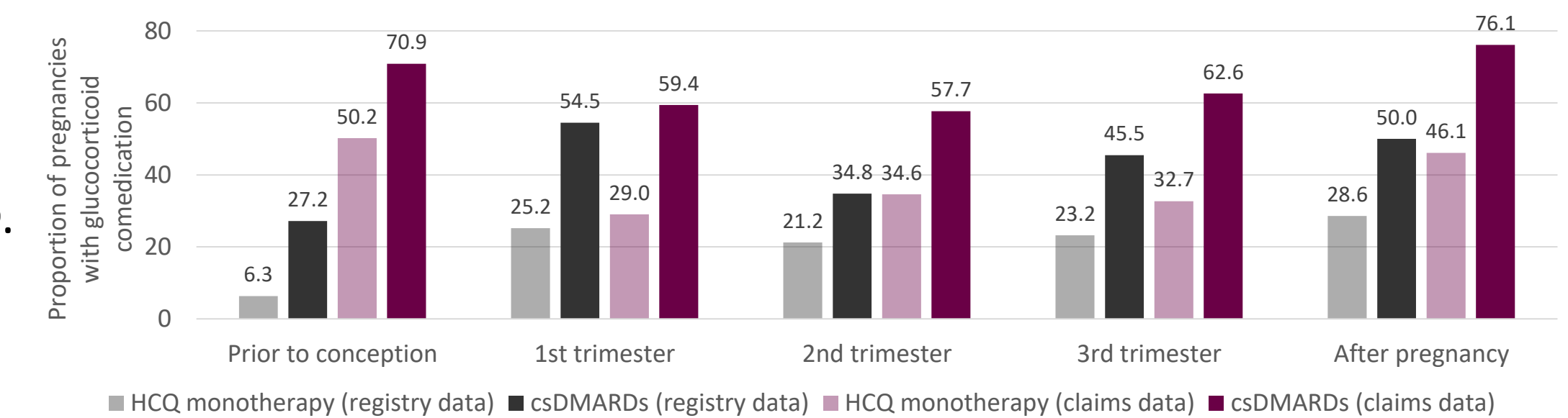
## Treatment patterns

- Treatment with non-steroidal anti-inflammatory drugs (NSAID), glucocorticoids (GC), hydroxychloroquine (HCQ) monotherapy, other csDMARDs (either mono- or combination therapy) and bDMARDs was investigated hierarchically.



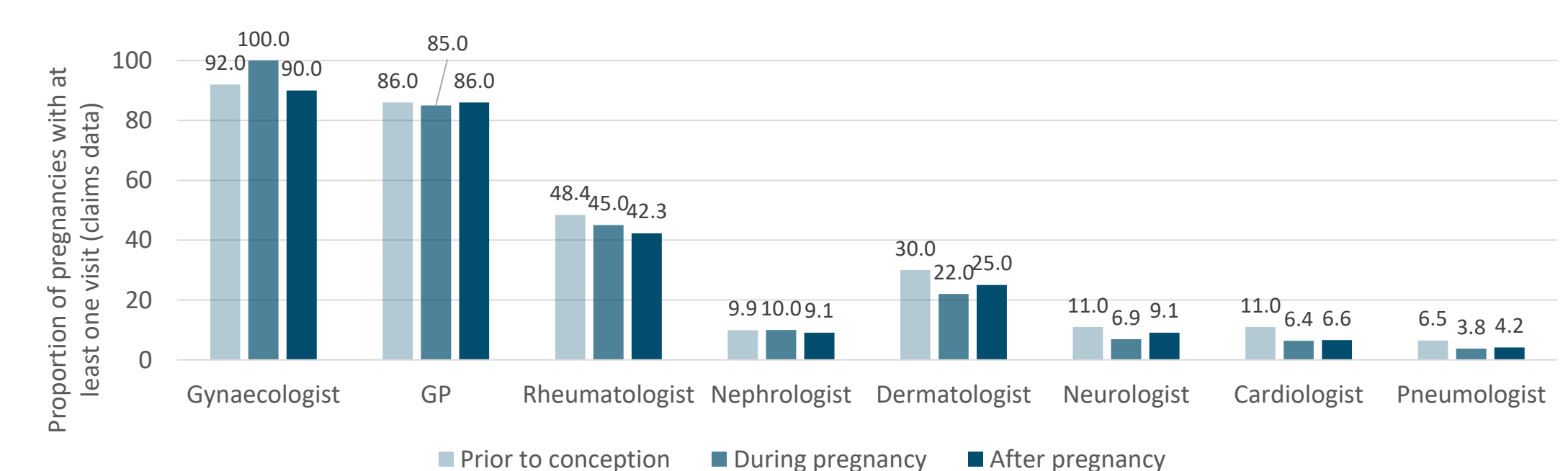
## Comedication with glucocorticoids

- A higher proportion of women in the claims data received glucocorticoids along with their csDMARD.
- In both databases, women received less glucocorticoid comedication prior to pregnancy.



## Medical care patterns

- In the claims data, 48% of women had at least one visit at the rheumatologist prior to pregnancy, and 45% during pregnancy (figure).
- In the registry, all patients were in rheumatology care during pregnancy; 77% received counselling by a rheumatologist and 69% by a gynaecologist prior to pregnancy.



## CONCLUSIONS

- Patients in the registry cohort showed more severe disease, yet achieved favourable outcomes, likely due to optimized care and well-controlled disease activity (mean physician-reported activity score [NRS 0-10] at conception of  $1.5 \pm 1.4$ ).**
- In claims data, APOs were more frequent despite presumably better baseline conditions.**
- Treatment patterns differed between the data sources with higher proportions of patients receiving no rheumatic treatment in the claims database, and more csDMARD use in the registry database.**
- Both data sources have their individual advantages and disadvantages: the registry provides detailed clinical insights, but represents a population under specialized rheumatology care, often with planned pregnancies and preconception counselling. Claims data offer a broader, population-based perspective but lack granular clinical detail.**

## FUNDING

This project is funded by the German Research Foundation DFG (project number 533620604). Rhekiss is jointly funded by the German Rheumatology Research Center Berlin and the Rheumazentrum Rhein-Ruhr e.V., Düsseldorf.

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