# LEVERAGING PRIMARY CARE PATIENT DATA TO INVESTIGATE THE EPIDEMIOLOGY OF SYSTEMIC LUPUS ERYTHEMATOSUS IN ITALY

P. FERRARA <sup>1,2</sup>, I.C. ANTONAZZO <sup>1,2</sup>, M. ZAMPARINI <sup>1</sup>, C. FORNARI <sup>1</sup>, C. BORRELLI <sup>3</sup>, S. BOARINO <sup>3</sup>, A. BETTIOL <sup>4</sup>, I. MATTIOLI <sup>4</sup>, P. PALLADINO <sup>5</sup>, E. ZANZOTTERA FERRARI <sup>5</sup>, G. EMMI <sup>4,6</sup>, L.G. MANTOVANI <sup>1,2</sup>, G. MAZZAGLIA <sup>1</sup>

- 1. Center for Public Health Research, University of Milan-Bicocca, Monza, Italy
- 2. Laboratory of Public Health, Istituto Auxologico Italiano IRCCS, Milan, Italy
- 3. Medical Affairs Department, AstraZeneca, Milan Italy
- 4. Department of Experimental and Clinical Medicine, University of Florence, Italy
- 5. Cegedim Health Data, Milan, Italy
- 6. Centre for Inflammatory Diseases, Monash University Department of Medicine, Monash Medical Centre, Clayton, Victoria, Australia

## INTRODUCTION

The significance of primary care databases (PCDs) is growing in informing epidemiological studies.

Systemic lupus erythematosus (SLE) is an autoimmune disease with a wide spectrum of clinical manifestation, which make the diagnosis of SLE particularly challenging. As a result, the studies that estimated incidence and prevalence of SLE have shown considerable variation.

Here, we utilized the Health Improvement Network (THIN®) database to explore the epidemiology of SLE in Italy and to gain insights into the demographic and clinical characteristics of newly diagnosed SLE patients.

# **METHODS**

A total of 634,753 eligible adult (≥18years) individuals were identified the Italian THIN® database, contributing data between 1st January 2017 and 31st December 2022, with at least one contact with a GP for any medical or administrative reason (i.e., the entry date) and with an available follow-back of at least three years.

To identify potential characteristics associated with SLE diagnosis and analyze comorbidity prevalence in incident SLE cases, patients were compared with four non-SLE controls from the same dataset, matched by age and sex.

To gain a deeper insight into the characteristics of SLE, the study considered three distinct case definitions (detailed in Reference #1): I) 'full systemic lupus', including the diagnostic codes (ICD-9CM) representing SLE or a subtype of SLE but excludes cutaneous-only lupus, as well as subjects meeting two or more criteria for SLE as defined by an adapted version of the EULAR/ACR criteria; II) 'systemic lupus code only', including diagnostic codes representing SLE or a subtype of SLE while excluding cutaneous-only lupus; III) 'fully comprehensive lupus', including subjects selected under the second definition, as well as those with cutaneous-only lupus or those meeting two or more criteria for SLE as defined by the adapted version of the EULAR/ACR criteria.

Standardized incidence and prevalence estimates were evaluated by computing age- and sex-specific rates, using the 2022 Italian population as the reference. Univariable and multivariable logistic regression models were used to investigate the association between SLE diagnosis and patients' demographic and clinical characteristics. Results were expressed as odds ratios (ORs) with 95% confidence intervals (CIs).

## RESULTS

A total of 191 incident cases and 1385 prevalent cases were identified in the study population using the first definition (Table 1; results for the alternative definitions are detailed in Reference #1).

In 2022, the incidence peaked in the 40–49-year age group for females, occurring and later among males. Additionally, it was greater in females compared to males for all ages (Fig. 1). Across all study years, prevalence was higher in females than in males, with a ratio of approximately 5 to 1.

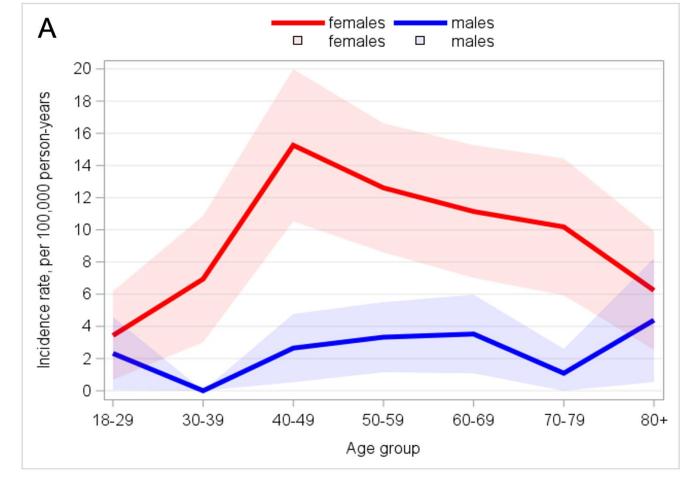
Compared to controls, mean age at diagnosis was 55.9 years and females accounted for 82.10% of SLE cases. Incidence exhibited geographic variation,

	Incidence				Prevalence		
Year	Incident cases	Person-years	Crude (95%CI)	Standardized (95%CI)	Prevalent cases	Crude (95%CI)	Standardized (95%CI)
2017	25	472,862	5.29 (3.21–7.36)	4.99 (4.79–5.18)	176	37.22 (31.72–42.72)	36.04 (35.51–36.57)
2018	28	482,920	5.80 (3.65–7.95)	5.46 (5.25–5.66)	198	41.00 (35.29–46.71)	39.75 (39.2–40.3)
2019	23	491,726	4.68 (2.77–6.59)	4.46 (4.27–4.65)	216	43.93 (38.07–49.78)	42.73 (42.15–43.3)
2020	26	495,645	5.25 (3.23–7.26)	5.07 (4.87–5.27)	233	47.01 (40.97–53.04)	46.13 (45.53–46.73)
2021	58	497,692	11.65 (8.65–14.65)	11.19 (10.89–11.48)	281	56.46 (49.86–63.06)	55.60 (54.95–56.26)
2022	31	458,820	6.76 (4.38–9.13)	6.51 (6.29–6.74)	281	61.24 (54.09–68.4)	60.57 (59.89–61.25)
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Table 1. SLE incidence (per 100,000 person-years) and prevalence (per 100,000 people) by year, 2017–2022 (first definition).

Source: Reference #1

being highest in Northern Italy (44.74%) and lowest in the South and the Islands (20.53%). At the time of diagnosis, 6.84% of cases had already registered at least one SLE symptom according to EULAR/ACR criteria. Individuals with SLE (vs. controls) had higher prevalence of certain comorbidities, such as chronic kidney disease (CKD; 5.79% vs. 1.45%), chronic hepatic disease (CHD, 6.32% vs. 1.97%) and osteoporosis (16.32% vs 9.47%), as well as concomitant autoimmune diseases, including rheumatoid arthritis (5.79% vs. 1.97%) and Sjögren's syndrome (3.68% vs. 0.39%). Results were confirmed by multivariate analyses, which found that at the time of SLE diagnosis, patients had higher significant odds of being previously diagnosed with CKD (OR 3.88; 95%CI 1.62–9.26), CHD (OR 2.93; 95%CI 1.31–6.59), rheumatoid arthritis (OR 2.55; 95%CI 1.09–5.95), Sjögren's syndrome (OR 6.66; 95%CI 1.63–27.29), as well as a higher odds of being prescribed with five or more concomitant therapies (OR 1.47; 95%CI 1.05–2.05).



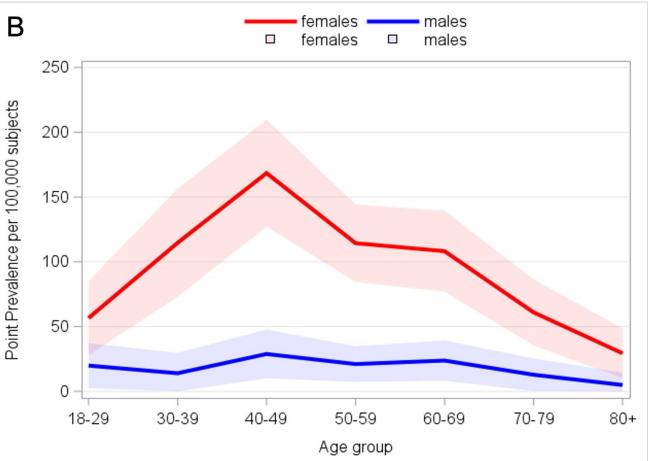


Figure 1. Line chart of sex- and age-specific incidence rate (Panel A) and point prevalence (2022; Panel B) for systemic lupus erythematosus. The lines represent the estimates, and the bands indicate the 95% confidence intervals.

Source: Reference #1

# CONCLUSIONS

This research marks the first comprehensive examination of SLE in Italy, showcasing an escalating trend in disease incidence in recent years.

This marks the inaugural comprehensive examination of SLE in Italy, showcasing an escalating trend in disease incidence in recent years. Factors such as age, sex, and geographical location seem to shape SLE epidemiology.

Through the lens of SLE, this study emphasizes the need to prioritize the utilization of PCD in analysing estimates, which can be leveraged to inform future healthcare planning.

## REFERENCES

1. Ferrara P, Antonazzo IC, Zamparini M, et al. Epidemiology of SLE in Italy: an observational study using a primary care database. Lupus Science & Medicine 2024;11(1):e001162. doi: 10.1136/lupus-2024-001162.

## **CONTACT INFORMATION**

Pietro Ferrara, MD PhD
Assistant Professor of Public Health
pietro.ferrara@unimib.it

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