



## Original article

## Prevalence of systemic lupus erythematosus in Spain: higher than previously reported in other countries?

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## Abstract

**Objectives.** Prevalence of SLE varies among studies, being influenced by study design, geographical area and ethnicity. Data about the prevalence of SLE in Spain are scarce. In the EPISER2016 study, promoted by the Spanish Society of Rheumatology, the prevalence estimate of SLE in the general adult population in Spain has been updated and its association with sociodemographic, anthropometric and lifestyle variables has been explored.

**Methods.** Population-based multicentre cross-sectional study, with multistage stratified and cluster random sampling. Participants were contacted by telephone to carry out a questionnaire for the screening of SLE. Investigating rheumatologists evaluated positive results (review of medical records and/or telephone interview, with medical visit if needed) to confirm the diagnosis. To calculate the prevalence and its 95% CI, the sample design was taken into account and weighing was calculated considering age, sex and geographic origin. Multivariate logistic regression models were defined to analyse which sociodemographic, anthropometric and lifestyle variables included in the telephone questionnaire were associated with the presence of SLE.

**Results.** 4916 subjects aged 20 years or over were included. 16.52% (812/4916) had a positive screening result for SLE. 12 cases of SLE were detected. The estimated prevalence was 0.21% (95% CI: 0.11, 0.40). SLE was more prevalent in the rural municipalities, with an odds ratio (OR) = 4.041 (95% CI: 1.216, 13.424).

**Conclusion.** The estimated prevalence of SLE in Spain is higher than that described in most international epidemiological studies, but lower than that observed in ethnic minorities in the United States or the United Kingdom.

**Key words:** systemic lupus erythematosus, prevalence, epidemiology

## Rheumatology key messages

- EPISER2016 has shown an SLE prevalence of 210 cases per 100 000 inhabitants (95% CI: 110, 400).
- SLE prevalence is higher than that described in most international epidemiological studies.

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## Introduction

SLE is a multi-systemic autoimmune disease with a complex and diverse nature in its clinical presentation. It occurs more frequently in young, fertile women and can appear in all ethnicities.

Prevalence of SLE varies among studies, being influenced by study design, geographical area and ethnicity. In the USA, a national population-based study with data from the Third National Health and Nutrition Examination Survey (NHANES III) estimated a prevalence of 241 cases/100 000 adults, based on self-reported physician-diagnosed SLE [1]. In a retrospective study in the UK, based on a longitudinal database of general practice records, it was 97 cases/100 000, being as high as 517.5/100 000 for people of Black Caribbean ethnicity [2].

Data published in literature about the prevalence of SLE in Spain are scarce and most of them are limited to very specific geographic areas [3, 4]. In 2000, the Spanish Society of Rheumatology (SER), through the EPISER2000 study, estimated a prevalence of SLE in the adult Spanish population of 91 cases per 100 000 inhabitants (95% CI: 30, 390) [5].

In the EPISER2016 study, a reissue of EPISER2000 promoted by the SER, the prevalence data of SLE in the general adult population in Spain has been updated, seeking to improve precision by increasing the sample size. Also, the extent to which different sociodemographic, anthropometric and lifestyle variables may influence this prevalence has been explored.

## Methods

The aims, methods and sample characteristics of the EPISER2016 study have been previously described [6, 7]. Briefly explained, it is a population-based, multi-center, cross-sectional study to estimate the prevalence of the major rheumatic diseases (RA; SLE; symptomatic osteoarthritis of the hand, knee, hip, cervical and lumbar spine; fibromyalgia; ankylosing spondylitis; psoriatic arthritis; Sjögren's syndrome; gout; and symptomatic osteoporotic fracture) in the adult population in Spain. As EPISER2016 included various diseases, for sample size calculation we focused on RA and PsA prevalence (election by convenience, based on the previous EPISER2000). Assuming a Poisson distribution, a sample comprising 4000 individuals would enable to obtain a 95% CI of 0.30, 0.77 for a prevalence of 0.5% (expected for RA) and of 0.14–0.54 for a prevalence of 0.3% (expected for psoriatic arthritis). Assuming 20% of missing values, it was considered necessary to include around 5000 individuals [6, 7].

Subjects were randomly selected by means of multi-stage stratified (strata based on rural/urban municipalities, sex and age) cluster sampling, who resided in 78 municipalities randomly selected throughout all the autonomous communities in Spain. In case of non-answered phone calls, a minimum of six attempts were

made in different time frames. If after these attempts there was no answer or the subject refused to participate, another phone number within the same municipality was randomly selected. Similarly, if any of the randomized municipalities were not representative of the autonomous community, mainly because of its sociodemographic characteristics such as a high percentage of foreigners or second homes, it was replaced by another randomly selected municipality of the same autonomous community [7].

In all locations, the participants were contacted by using random digit dialling and a Computer Assisted Telephone Interviewing system (CATI) to conduct a questionnaire for the screening of the diseases under study. The survey was mostly performed via landlines, but in order to facilitate access to younger patients and expand the registry, we have incorporated mobile phones since March 2017, which represent 20.3% of the final sample. This figure reflects the proportion of homes in Spain that relied solely on a mobile telephone connection [7]. Both for the randomized selection of telephones in each municipality as well as for conducting the initial screening interviews, an external company working in sociological studies was involved, with experience in the area of health and call centre services (Ipsos España).

The screening considered two complementary paths. First, participants were asked if they had already been diagnosed with any of the diseases under study. Then, a screening was carried out based on symptoms (see [Supplementary Material](#), section Questionnaire of the call centre for symptom-based screening, available at *Rheumatology* online, for SLE symptom-based screening).

If participants reported to be diagnosed with any of the diseases under study, they were requested to consent for the rheumatologists who were participating as researchers at the municipality's referral hospital to confirm this diagnosis in their clinical records. Individuals who did not mention that they were previously diagnosed, but who presented positive results in the symptom-based screening, were again interviewed via telephone by the investigating rheumatologist to assess the suspicion by carrying out a second questionnaire (see [Supplementary Material](#), section Telephone questionnaire used by rheumatologist to study the suspicion, available at *Rheumatology* online, for the SLE questionnaire). If the suspicion was maintained, a medical appointment was arranged to complete the process of diagnosis confirmation (physical examination and complementary tests), according to the 1982 SLE ACR criteria (these were used in the EPISER2000) and the 2012 SLICC criteria [8, 9].

These criteria were used in the confirmation of cases that were not diagnosed before the study. For subjects who were already diagnosed beforehand, it was not actively required to look over their clinical records to comply with the criteria; clearly identified diagnoses were accepted, regardless of the criteria used.

Cases in which the subject completed the call centre interview with a positive result for the screening of SLE and the rheumatologist could not confirm or rule out the diagnosis were considered missing.

The oral informed consent of all subjects was requested upon first telephone contact. Additionally, written informed consent was requested for all those who went to the participating centres for a physical examination and complementary testing. The study was approved by the Clinical Research Ethics Committee (CREC) of Hospital Universitario de Canarias (Acta 12/2016), which acted as the CREC of reference, and the CRECs of the participating centres that so required it.

### Patient and public involvement (PPI)

There were no funds or time allocated for PPI so we were unable to involve patients. We have invited patients to help us develop our dissemination strategy.

### Statistical analysis

To calculate the prevalence and its 95% CI, the sample design was taken into account. The weights were calculated depending on the selection probability in each of the stages of the sampling, taking as a reference the distribution of the population in Spain according to census data from the Spanish Institute of Statistics. This weighing was carried out considering age, sex and geographic origin (three zones were defined: North [Galicia + Asturias + Cantabria + Basque Country + Navarre + La Rioja], Mediterranean and the Canary Islands [Catalonia + Valencian Community + Balearic Islands + Murcia + Andalusia + Canary Islands] and Centre [Community of Madrid + Castile and León + Aragón + Castile-La Mancha + Extremadura]).

Finally, predictive models were defined to analyse which sociodemographic, anthropometric and lifestyle variables included in the first phone questionnaire were associated with the presence of SLE. To that end, first, bivariate analysis was carried out on the association of the disease to each of the variables and then binary logistic regression models were constructed using those variables with a  $P$ -value of  $<0.2$  in bivariate analysis (age and sex were included in the model, regardless of the  $P$ -value in bivariate analysis). Statistical significance was defined as  $P < 0.05$ . The analyses were performed using IBM SPSS Statistics v22.

## Results

A total of 84 098 different phone numbers were dialled from November 2016 to October 2017. Of these, 50 170 were wrong numbers or were unanswered; 28 784 individuals refused to participate (27 895 or 96.9% from the very beginning of the interview); in all 5144 interviews were completed (thus, the response rate once the subject had answered the phone call was 15.2%). After eliminating duplicate interviews or excess numbers from certain sample strata, 4916 individuals were included in

the final analysis. Baseline characteristics of the sample and a comparison with the general population aged 20 years or older in Spain (reference population in EPISER2016) have been published in detail elsewhere [7].

After the first phone call, 16.52% (812/4916) of individuals had a positive screening result for SLE. Of these, 6.77% (55/812) were missing. Twelve cases of SLE (10 women, 2 men) were detected, of which 91.67% (11/12) had been diagnosed prior to the EPISER2016 study. The estimated prevalence was 0.21% (95% CI: 0.11, 0.40).

The positive predictive value of the SLE screening questionnaire carried out by the call centre was 1.45% (11 cases of SLE among the 757 subjects with positive screening who completed the study). The remaining case, not detected in the SLE screening, was a 37 year-old woman, who had been diagnosed prior to the study and with a negative screening result for all the diseases included in the EPISER2016 study, except for the symptomatic screening for Sjögren's syndrome.

Negative predictive value among those with positive screening result for any of the other rheumatic diseases (not SLE) included in EPISER2016 was 99.95% ( $n = 1862/1863$ ). In a pre-planned substudy on 209 subjects randomly selected among those with a negative screening result for all the diseases, no cases of SLE were detected.

### Bivariate and multivariate analysis

Bivariate and multivariate analyses were limited by the low number of SLE cases in the sample. Table 1 shows the  $P$ -values of the associations found in bivariate analysis between the presence of SLE and sociodemographic, lifestyle and anthropometric variables included in the questionnaire carried out by the call centre.

Table 2 includes the results of multivariate analysis. The type of municipality showed a statistically significant association with the presence of SLE ( $P = 0.023$ ), being more prevalent in the rural municipalities, with an odds ratio (OR) = 4.041 (95% CI: 1.216, 13.424).

## Discussion

The prevalence of SLE varies between the different geographical areas of the world that have been studied. In Spain, Gómez *et al.* described a prevalence in 2003 of 31.7 cases per 100 000 inhabitants (95% CI: 28.3, 35.0) [4]. Alonso *et al.* carried out an epidemiological study in 2006, describing a prevalence of 17.5 cases per 100 000 inhabitants (95% CI: 12.6, 24.1) [3], slightly lower than the prevalence cited in the study by Gómez *et al.* Both studies accounted for cases that were already diagnosed, detected in the review of medical records, and are limited to parts of north-western Spain.

The EPISER2000 study (carried out in 1998–99) found a prevalence of SLE in the adult Spanish population of

91 cases per 100 000 inhabitants (95% CI: 30, 390), markedly higher than the previously mentioned data from our country [5]. The EPISER2000 was based on a

**TABLE 1** Association between the presence of SLE and sociodemographic, lifestyle and anthropometric variables; bivariate analysis

Variable	SLE cases	Subjects without SLE	P-value
Age			0.34
20–39	25.0%	32.0%	
40–59	58.3%	38.4%	
60+	16.7%	29.6%	
Sex, female	83.3%	54.2%	0.043
Zone of Spain			0.50
North	41.7%	28.6%	
Mediterranean and Canary Islands	41.7%	41.9%	
Centre	16.7%	29.5%	
Residence in an urban municipality	50%	77.5%	0.034
Birth abroad	8.3%	6.9%	0.58
Level of studies			0.093
Basic	27.3%	37.3%	
Intermediate	54.5%	26.0%	
Higher	18.2%	36.6%	
Smoking habit			0.99
Never smoker	50.0%	49.1%	
Former smoker	25.0%	26.8%	
Smoker	25.0%	24.1%	
BMI			0.094
Normal weight (18.5 ≤ BMI < 25)	45.5%	44.4%	
Underweight	9.1%	1.2%	
Overweight (25 ≤ BMI < 30)	27.3%	39.6%	
Obesity (BMI ≥ 30)	18.2%	14.8%	

relatively small sample size, due to which its increase in the EPISER2016 makes its results more precise.

The estimated prevalence of SLE in the EPISER2016 study is 210 cases per 100 000 inhabitants (95% CI: 110, 400). In general, this prevalence is higher than that described in other geographical areas, with the exception of that obtained in a North American study [1]. This population-based study used the data from a national survey in the first half of the 1990s, the Third National Health and Nutrition Examination Survey (NHANES III), to calculate the prevalence of SLE in the United States, based on self-reported physician-diagnosed cases. The estimated prevalence was 241 cases per 100 000 adults aged 17 years or older (95% CI: 130, 352), which fell to a value of 53.6 per 100 000 (95% CI: 12.2, 95.0) if furthermore the criterion was added to take into account the prescription of antimalarials, glucocorticoids or immunosuppressants.

In the United Kingdom, a retrospective study used a Primary Healthcare longitudinal database, the Clinical Practice Research Datalink (CPRD), considered to be representative of the population of the United Kingdom, to calculate the prevalence of SLE in the period from 1999 to 2012, stratified by year, age group, sex, region and ethnicity [2]. The authors found a lower prevalence than observed in the EPISER2016, but higher than that described in most published series in literature [10]. The prevalence in this study increased throughout time, from 64.9 cases per 100 000 inhabitants (95% CI: 62.0, 67.9) in 1999 to 97.0 per 100 000 (95% CI: 94.1, 99.9) in 2012. For certain ethnic groups, a prevalence of SLE was observed that was even higher than that described in the EPISER2016. Thus, for the black population of Caribbean origin, it was 517.5 cases per 100 000 inhabitants in 2012 (95% CI: 398.5–660.8), and for the black population of non-Caribbean or African origin, 325.5 cases per 100 000 inhabitants (95% CI: 231.4, 496.2) [2].

**TABLE 2** Variables associated with the presence of SLE. Multivariate analysis

Variables	OR	95% CI		P-value	
		Lower	Upper		
Age	From 20 to 39 <sup>a</sup>				
	From 40 to 59	1.449	0.343	6.118	0.61
	≥60	0.332	0.030	3.733	0.37
Sex	Female	3.498	0.710	17.246	0.12
Rural/urban	Rural	4.041	1.216	13.424	0.023
Level of studies	Basic <sup>a</sup>				
	Intermediate	2.532	0.596	10.756	0.21
	Higher	0.585	0.090	3.805	0.58
BMI	Normal weight <sup>a</sup>				
	Underweight	6.642	0.714	61.792	0.096
	Overweight	0.833	0.194	3.584	0.80
	Obese	1.518	0.286	8.065	0.62

<sup>a</sup>Category of reference.

OR: odds ratio.

Of particular interest is a Greek community-based study, in which using a method of active detection of SLE cases from different sources (they only took into account previously diagnosed cases), they observed a steady increase in the crude prevalence of SLE. Thus, in 1999 it was 22 (95% CI: 18, 26) cases per 100 000 inhabitants aged 15 years or older, against 143 (95% CI: 133, 154) in 2013 [11]. This latter prevalence is closer to that estimated in our study, considering that the Greek study included people between 15 and 20 years old and this age group would have lower prevalence rates [12, 13].

The symptom-based screening enabled detecting 1 of the 12 cases in the EPISER2016 study that was not previously diagnosed. This fact would contribute to explain part of the higher prevalence of SLE compared with other studies based on the review of various databases.

According to published data, annual frequency of hospital admissions in patients with SLE in Spain (assessed as the number of hospital admissions divided by the number of patients with SLE) was around 9.5% in 2015 [14]. In the Registry of Hospital Discharges of the National Health System, which includes 93% of hospital discharges documented in Spanish hospitals (<https://pes.tadistico.inteligenciadegestion.mscbs.es/publicoSNS/Comun/ArbolNodos.aspx?idNodo=6383>) that year, there were 6744 admissions with one diagnosis code corresponding to SLE (710.0 in the ICD-9-CM) in the general population aged 20 years or older. Based on the SLE prevalence estimated by EPISER2016 (0.21%), there should have been 78 644 SLE patients aged 20 years or older in Spain (37 449 402 global population in 2015). If the annual frequency of hospital admissions in patients with SLE was 9.5%, as previously mentioned, and according to EPISER2016 data, there should have been 7471 hospital admissions in Spain, a figure that is close to 6744. These data suggest that the prevalence of SLE as detected by EPISER2016 does, in fact, reflect the reality of this disease in Spain.

EPISER2016 was designed to determine the global prevalence of several rheumatic disease in Spain. The analysis of the association with sociodemographic, anthropometric and lifestyle variables was a secondary objective and for pathologies with a low prevalence, such as RA, Sjögren's syndrome or SLE, the statistical power for this analysis is very limited. Taking into account this fact for the interpretation, we observed the greatest frequency of the disease in women, in line with all published series in literature; the magnitude of the association in the multivariate analysis would be in the lower part of the range reported in the literature (a prevalence ratio as low as 3.6:1 has been reported in Germany) [10, 12, 15]. We also observed that SLE is more prevalent in Spain in rural areas in comparison to urban areas, with an OR of 4.041, even though due to the very few cases of SLE the estimate would be quite imprecise (95% CI: 1.216, 13.424). There is little data in literature in this regard but, in general, contrary to our study, it is agreed that SLE is more prevalent in urban than in rural regions [11, 16, 17]. In the previously

mentioned Greek study, the prevalence was 165 per 100 000 in urban regions vs 123 per 100 000 in rural regions ( $P < 0.001$ ) [11]. It is difficult to interpret these discordant results, which deserve a more detailed analysis in future epidemiological studies.

As a limitation of the study, though the sample size was increased more than double in comparison with EPISER2000, the low prevalence of SLE entails relatively wide CI. Nevertheless, this is similar to that estimated in the USA and its lower limit is above the higher limit of CIs in most recent studies from other countries [1, 15]. Among the strengths of our study, it should be highlighted that criteria for SLE symptomatic screening used in the first phone call allowed a very high sensitivity.

Telephone surveys have become an accepted method for prevalence studies on rheumatic diseases [18–21]. The response rate for calls in EPISER2016 was 15.2%, which could be interpreted as a possible source of bias. However, this response rate is consistent with other recent population-based telephone surveys for prevalence analyses and was possibly lower compared with other studies due to the demanding sampling requirements (strata based on rural/urban, sex and decades of age) [22–25]. In the last decades, epidemiological studies in developed countries have been hampered by a marked decline in participation levels, and thus their importance in terms of the validity of estimates remains an open question. Different reports concerning this issue have concluded that a low response rate, in and of itself, does not necessarily induce bias when the reasons for non-participation are unrelated to the variables of interest in the study [22, 26–28]. In this regard, self-reported data on osteoarthritis, chronic cervical pain and chronic lumbar pain available from the 2017 National Health Survey of Spain, a survey boasting rigorous sampling procedures, are similar to those that were initially self-reported by the subjects in EPISER2016 (20, 6% vs 18, 4%; 17, 4% vs 13, 5%; 21, 7% vs 18, 4%, respectively) [7, 29]. This would support the view that the possible reasons for refusing to participate in EPISER2016 are not associated with its primary objective, therefore indicating that the participation rate is unlikely to be a significant source of bias in our study.

In conclusion, the EPISER2016 study has shown a SLE prevalence in Spain of 210 cases per 100 000 inhabitants (95% CI: 110, 400). This prevalence is higher than that described in most international epidemiological studies, but lower than that observed in different ethnic minorities in the United States or in the United Kingdom. We observed a higher prevalence of SLE in rural than in urban environments. This finding is contrary to that usually described in literature in this regard and deserves to be more specifically evaluated in upcoming epidemiological studies.

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## Supplementary data

Supplementary data are available at *Rheumatology* online.

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