Prevalence of sicca syndrome in the Peruvian population

L.A. Moreno-Quispe¹,², I.V.N. Velarde-Grados¹,
M. Guzmán-Avalos³, L. de Arriba¹, R.M. López-Pintor¹

ABSTRACT

Objective. Sjögren’s syndrome is a complex and heterogeneous autoimmune disease characterised by ocular and oral dryness, which mainly affects the exocrine glands. The objective of this study was to determine the prevalence of sicca syndrome (SS) in the Peruvian population. The age and gender of patients with SS and their national prevalence and in each of the departments were defined.

Methods. This was a cross-sectional prevalence study. All the people for whom the Ministry of Health (MINSA) in Peru covered health treatments from January to December 2016 were taken into account. The patients with SS were either newly or previously diagnosed with sicca syndrome (Sjögren’s) according to the international classification of diseases version 10 (ICD-10) of the World Health Organisation (WHO). The prevalence was determined considering the number of cases of SS in the total population registered by the Ministry of Health (MINSA).

Results. 1,301 cases of SS were observed in a total population of 15,417,345 people served in 25 territories. The prevalence of SS in this population was 0.0084%, the prevalence rate was 8.4 cases per 100,000 persons (95% CI: 7.99–8.91). The prevalence of SS was higher in the territories of Tacna, Lima, La Libertad, Arequipa, Callao, and Apurímac.

Conclusion. The results of this study show the prevalence of SS in the Peruvian population and serve to strengthen the health strategies of rheumatology, ophthalmology, and oral health to improve the diagnosis, treatment, follow-up of the disease, and the quality of life of patients with SS.

Introduction

Sjögren’s syndrome is a chronic autoimmune rheumatological disease that presents with oral and ocular dryness that diminishes the quality of life of patients. The symptomatology of the disease is complex and heterogeneous (1), which hinders its correct diagnosis and treatment. The disease is classified into two types: the primary Sjögren’s syndrome (pSS) that is characterised by dry mouth and eyes without accompanying rheumatic disease and the secondary Sjögren’s syndrome (sSS) that is associated with other connective tissue diseases (2-4). In some cases, SS is accompanied by sensory and motor neuropathies, fibromyalgia, risk of cardiovascular diseases, and interstitial lung disease (5-9). pSS is a disease of universal distribution and is one of the most frequent autoimmune diseases, with an estimated prevalence in the general population of 60.82 cases (95% CI 43.69–77.94) per 100,000 persons (10).

Funding: this article has been developed thanks to the financing of Fondecyt, initiative of the National Council of Science, Technology and Technological Innovation (CONCYTEC). Contract n° 227-2015-FONDECYT.

Competing interests: none declared.
can be observed, in which these glands are slightly enlarged, firm, and painful on palpation. In addition, there is an increased risk of developing non-Hodgkin’s lymphoma (17, 18).

At the ocular level, the disease manifests as a grit, absence of tearing, excessive blinking, fatigue and reduction of visual acuity, photosensitivity, and dry keratoconjunctivitis, which can in some cases destroy the cornea.

Not all studies use the same criteria to diagnose SS. The most frequently used are the criteria of the European-American Consensus of 2002 (19) and the classification criteria of the SICCA group of 2012 (Sjögren Internacional Collaborative Clinical Alliance) (20). In 2016, new joint criteria between the ACR (American College of Rheumatology) and the EULAR (European League against rheumatism) was suggested which will probably be the most used in the future (21).

To date, there is no definitive cure for SS and more treatment options are needed (22). Currently the treatment is aimed at symptoms associated with xerostomia and xerophthalmia. Treatments recommended for these patients include: salivary and tear moisturising substitutes, balanced diet, periodic fluoridation, and control reviews to prevent the appearance of a possible lymphoma (23). In cases of intolerance to standard of care, therapies directed to B cells may be considered in patients with severe and refractory systemic disease, although there are several controversies (24). Pilocarpine may also be recommended as long as the residual salivary gland is functioning (16).

The most relevant and good quality epidemiological studies on the disease have been carried out in more advanced countries such as Greece with a prevalence rate of 86.40 (95% CI: 78.16–94.64) (25), France 11.34 (95% CI: 9.42–13.27) (26), Italy 30.91 (95% CI: 9.49–52.32) (27), Norway 49.75 (95% CI: 45.01–54.48) (28), Denmark 47.79 (95% CI: 45.96–49.62) (29), and Taiwan 58.30 (95% CI: 53.57–63.03) (30) for each 100,000 people respectively. In Brazil, a prevalence rate of 60.82 (95% CI: 43.69–77.94) was reported (31), but in other countries of South and Central America there are no studies on the subject. Therefore, the objective of our work was to estimate the prevalence of SS in the Peruvian population and in its different territories. In the same way, the distribution of the disease by sex and age was also studied.

### Material and methods

This is a cross-sectional prevalence study. To this end, the population that received health coverage during 2016 in the MINSA service in Peru was taken as a reference. To calculate the prevalence, patients with a diagnosis of SS were classified according to the M35.0 nomenclature of the Sicca Syndrome (Sjögren) of the ICD-10 of the WHO using the MINSA. In order to obtain the data, the external consultation records of the MINSA health establishments of the 25 departments nationwide were used. Newly or previously diagnosed patients were included. Prevalence was defined as the proportion of individuals with SS in the total of the Peruvian population treated at the national level by the Ministry of Health during the year 2016.

The collection of the information was authorised through documents no. 17-008380 and no. 18-002028. Patient data was treated according to the Helsinki Declaration of 1975/83 and its subsequent revisions, and according to Legislative Decree no. 1353 of the National Authority on Transparency and Access to Public Information, which strengthens the protection regime of personal data applicable in Peru based on the characteristics of this study.

The variables collected for this study, in addition to the diagnosis of SS, were the age and sex of the patients. The age variable was categorised by groups: 0–11 years, 12–17 years, 18–29 years, 30–59 years and >60 years, respectively, due to the organisation of data per life cycle of the Peruvian Public Health System.

### Statistic analysis

The prevalence was calculated as a percentage. We also estimated the prevalence rate in cases per every 100,000 people and the 95% confidence interval (CI).
I & interval of confidence 66 sicca syndrome.

Clinical and Experimental Rheumatology 2019

The prevalence of 66 in Peru where a study identified 1,301 people newly or previously diagnosed with SS during the study period, of whom 82% were women and 18% were men. The female/male ratio was 2.79 (95% CI: 2.43–3.21).

Regarding the age of patients with SS, 48 cases (4%) were observed in an age range of 0–11 years, 20 cases (2%) in ages between 12–17 years, 101 cases (8%) in 18–29 years, 676 cases (52%) with ages between 30–59 years, and 456 cases (35%) older than 60 years.

The territories with the highest prevalence rate of SS were Tacna with 54 cases (95% CI: 45.38–64.14), Lima with 20.1 cases (95% CI: 18.68–21.68), La Libertad with 14.9 cases (95% CI: 12.58–17.58), Arequipa with 13.7 cases (95% CI: 11.37–16.46), Callao with 10 cases (95% CI: 7.64–13.01), and Apurímac with 6.8 cases (95% CI: 4.56–10.10) per 100,000 people.

### Discussion

This study is the first work that shows the prevalence of SS in Peru where a prevalence of 0.0084% or a prevalence rate of 8.4 cases per every 100,000 persons were observed. These results differ from other studies that show a much higher prevalence. For example, there are studies conducted in advanced countries such as Norway and Italy, reported by Goransson et al. and Sardu et al., which showed a prevalence rate of 49.75 (95% CI: 45.01–54.48) and 30.91 (95% CI: 9.49–52.32) per 100,000 persons-year respectively (27, 28).

Similarly, Eaton et al. reported a prevalence rate for SS of 47.79 (95% CI: 45.96–49.62) in Denmark and See et al. reported a prevalence rate of 58.30 (95% CI: 53.57–63.03) in Taiwan per 100,000 persons, respectively. These two studies used the WHO ICD registry (29, 30). However, the results of our study are closer to the study by Maldini et al. in France where they obtained a prevalence rate of 11.34 (95% CI: 9.42–13.27) per 100,000 persons (26). There is no data on the SS prevalence rate in non-advanced countries, except the study of Valim et al. that reported a prevalence rate of 60.82 cases per 100,000 persons-year in Brazil using the 2002 SS criteria (31). The low prevalence rate of SS observed in Peru in comparison with advanced countries could be due to the greater number of aging population and especially women who live in advanced countries (32).

These important variations may be also due to the diagnostic criteria of the SS used. In this case, it is known that the registration was made following the WHO ICD-10, but the criteria followed for the diagnosis of SS in each of the centres or patients is not known. Although the purpose of this study has been to provide epidemiological information about SS in Peru, it is important to achieve a registry of the diagnostic criteria used in the future in order to know if patients have been diagnosed correctly. Therefore, it would be necessary to make an effort for the specialists in rheumatology and the Peruvian Health System to register patients correctly following the current SS criteria.

At the institutional level, the Peruvian Health System is made up of health services provided by the Ministry of Health and regional governments, the Ministry of Defense, the Ministry of the Interior and private health companies. In our study, the population of the Ministry of Health and regional governments were only studied. It was not possible to collect information from the other institutions.

The WHO ICD-10 disease registry whose nomenclature is “M35.0 syndrome sicca (Sjögren)” does not separate between pSS and sSS. As we saw, pSS and sSS are two distinct entities and the new classification criteria for the disease take in account these SS types (19–21). MINSA data does not show the SS type. We suggest diagnosing SS patients correctly defining and recording SS type. These modifications could contribute to the standardisation of registration methods at a national and global level in accordance with the corresponding scientific advances for the SS (19, 20).

In our study, a female/male ratio (M/H) in the prevalence rate of 2.79 (95% CI: 2.43–3.21) was observed. This number is close to the reports by Sardu et al. and Valim et al. in Italy and Brazil that showed a female/male rate of

Table II. Prevalence rates of sicca syndrome by age and gender groups of the study.

<table>
<thead>
<tr>
<th>Age range</th>
<th>Peruvian population (Total)</th>
<th>General population MINSA</th>
<th>Cases of SS (Total)</th>
<th>Cases of SS</th>
<th>Population MINSA</th>
<th>Rate of prevalence CI:95%</th>
<th>Cases of SS</th>
<th>Population MINSA</th>
<th>Rate of prevalence CI:95%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>2016</td>
<td>15417345</td>
<td>1301</td>
<td>1061</td>
<td>9449495</td>
<td>11 (10.57-11.92)</td>
<td>240</td>
<td>5967850</td>
<td>4 (3.54-4.56)</td>
</tr>
</tbody>
</table>

IC: interval of confidence; SS: sicca syndrome.
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2.48 (95% CI: 0.50–12.29) and 4.81 (95% CI: 0.23–100.25), respectively (27, 31). However, the majority of SS prevalence studies showed a greater female/male ratio that varies between 8.7 to 17.27 (26, 30).

There are studies that observed how the prevalence of SS increases with age (33). Similarly, Goransson et al. showed that the average age of patients with pSS was 61.6±13.2 years (28). Maciel et al. also observed in his study that 86% of pSS cases corresponded with a mean age of 64.6±15.2 years (34). Regarding the age, the greater part of our patients was between 30–59 years old (52%) and older than 60 years old (35%). In this case, the average age of the patients could not be obtained, since the Peruvian Health System registered age in categories. It would be more convenient to record age in years, since the age in categories. It would be more convenient to record age in years, since the age ranges shown in the MINSA registry are very broad, to give a clear view of the average age of patients with SS in Peru.

The Peruvian departments with the highest prevalence of SS were Tacna, Lima, La Libertad, Callao, Arequipa, and Apurimac. This may respond to the highest prevalence of SS: Tacna, Lima, La Libertad, Apurimac, and Callao. Knowledge of this disease must be promoted in the Peruvian health system, and it is essential that patients with SS potential receive the necessary diagnostic techniques to be able to make an early diagnosis of the disease following the current criteria. It is necessary to promote health policies and resources aimed at improving the diagnosis and treatment of the disease to improve the quality of life of these patients.

Acknowledgement

Thanks to the staff of the company Innovación y Desarrollo Peru SAC, to the Santiago Antúnez de Mayolo University and to the personnel of the MINSA for their collaboration in the access to public information to carry out the study.

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