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Estimating the prevalence of Sjogren's syndrome in the world using systematic review and meta-analysis

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ABSTRACT

Introduction: Sjogren's syndrome is an autoimmune disorder with variable prevalence in different parts of the world. This study aims to estimate the prevalence of Sjogren's syndrome worldwide using a systematic review and meta-analysis.

Materials and Methods: For this study, we searched the databases of PubMed, ProQuest, Cochrane, Web of Science, and the Google Scholar search engine without any time limit until February 17, 2024. We used STATA 14 software for data analysis, and the significance level was set at $P<0.05$.

Results: Combining the findings of 24 observational studies with a total of 211349 participants, we concluded that the overall prevalence of Sjogren's syndrome in the world and the female population was (13%; [95% CI: 10%, 16%]) and (15% [95% CI: 4%, 26%]), respectively. The worldwide prevalence of Sjogren's syndrome in cohort studies and cross-sectional studies was (14% [95% CI: 10%, 19%]) and (10% [95% CI: 7%, 14%]), respectively. However, the prevalence of primary Sjogren's syndrome was (7% [95% CI: 5%, 9%]) and the prevalence of secondary Sjogren syndrome was (9% [95% CI: 6%, 13%]). Additionally, the prevalence of Sjogren's syndrome among the age groups of 20-29, 30-39, 40-49, 50-59, 60-69, and 70-79 years was (31% [95% CI: 30%, 42%]), (4% [95% CI: 1%, 6%]), (7% [95% CI: 5%, 10%]), (24% [95% CI: 15%, 33%]), (22% [95% CI: 2%, 42%]), and (5% [95% CI: 1%, 9%]), respectively.

Conclusion: Sjogren's syndrome has a high overall prevalence in the world, and considering the adverse outcomes of this disease, there should be measures taken to control and screen the prevalence of Sjogren's disease.

Registration: This study has been compiled based on the PRISMA checklist, and its protocol was registered on the PROSPERO (ID: CRD42024513783) and Research Registry (UIN: reviewregistry1793) website.

Implication for health policy/practice/research/medical education:
In a meta-analysis study, we found that in a global context, Sjogren's syndrome impacts 13% of the population, with a slightly elevated prevalence among females, affecting 15% of women. Notably, individuals aged 50–59 face a heightened susceptibility, with a risk that is double the general global prevalence of Sjogren's syndrome.

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Meta-analysis

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Introduction

Sjogren's syndrome is a chronic autoimmune systemic disease that disrupts the exocrine glands, such as the salivary and lacrimal glands. Sjogren's syndrome is divided into two types; the primary Sjogren's syndrome, which is a standalone disease, and the secondary Sjogren's syndrome which usually accompanies other autoimmune diseases like systemic lupus erythematosus, rheumatoid arthritis, and primary biliary cholangitis (1,2). Sjogren's syndrome can occur at any age, but people aged 40 to 50 years face the highest risk. Further, Sjogren's syndrome affects both genders but occurs more in the female population, thence the female-to-male ratio is 9:1 (3).

In previous studies, the prevalence of primary Sjogren's syndrome ranged from 2% (4) to 53% (5), and the prevalence of secondary Sjogren's syndrome varied from 4% (6) to 35% (7). Patients affected by Sjogren's syndrome suffer from physical and mental difficulties such as fatigue and depression, and the disease engraves their daily lives and work capacity (8). Although xerostomia and xerophthalmia are prominent symptoms of Sjogren's syndrome, 30–50% of patients face a systemic disease that affects various organs (e.g., the nervous system, lungs, joints, and kidneys) (9). Moreover, patients with Sjogren's syndrome have a higher risk of developing other diseases like non-Hodgkin lymphoma compared to the general population (10). Likewise, Sjogren's syndrome is linked with other autoimmune rheumatologic diseases, including systemic lupus erythematosus and rheumatoid arthritis (11). In addition, patients affected by the primary Sjogren's syndrome suffer a significant financial burden and limitations in work capacity due to pain and physical ability decline (12). Considering the aforementioned adverse effects and the variety of reported prevalences of Sjogren's syndrome in different studies, we conducted the present study to estimate the overall prevalence of Sjogren's syndrome throughout the world. We used the systematic review and meta-analysis methods to combine the results of the previous studies.

Materials and Methods

Study protocol

In this study, we investigated the worldwide prevalence of Sjogren's syndrome. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol (13), which is specific to systematic reviews and meta-analysis, and we registered the study protocol on the PROSPERO (the international prospective register of systematic reviews) website.

PICO variables

- **Population**: We imposed no restrictions on the participants based on gender or geographical region, and we investigated the whole human population.
- **Intervention**: None.
- **Comparison**: None
- **Primary outcome**: The global prevalence of Sjogren's syndrome was our primary outcome. The secondary outcomes were: the prevalence of Sjogren's syndrome based on age groups, gender, syndrome type (primary or secondary), and the study type.

Search strategy

To find the references in this meta-analysis, we used the keywords (prevalence, Sjogren's syndrome, and Sicca syndrome) and their MeSH (Medical Subject Headings) terms to search the international databases of ProQuest, PubMed, Web of Science, and Cochrane and the Google Scholar search engine without any time limitation until February 17th, 2024. We used the Boolean operators ("AND", "OR") to combine the keywords in the mentioned databases. Further, we manually investigated the list of references in the studies obtained by the electronic search. The search strategy in the PubMed database was the following: (Prevalence [Title]) AND (Sjogren's Syndrome [Title] OR Sicca Syndrome [Title]).

Inclusion and exclusion criteria

We included cohorts and cross-sectional studies that investigated the prevalence of Sjogren's syndrome. Thus, we excluded the following studies; those with nonrandomized sampling, non-observational studies, letters to the editor, those that did not report the data about sample size or the prevalence of Sjogren's syndrome, those that reported the data as their frequency, those without a complete text, low-quality studies, and narrative reviews.

Qualitative assessment

Two independent authors (Sh.B. and F.Y.) used the Newcastle-Ottawa Scale (NOS) checklist to investigate the quality of the studies. They implemented a star system for the checklist so that each question had a maximum of one star (except the comparison question, which could receive two stars). Hence, the minimum score was 0 (lowest quality), and the maximum score was 10 (highest quality). We included the studies with a score of more than 6 in our meta-analysis as high-quality studies (14).

Extracting the data

Two authors (A.N. and A.A.) simultaneously and separately performed this step to decrease the possibility of bias in data collection. Researchers had a data extraction table that included the following variables: author's name, study type, sample size, number of males and females, year of publication, mean age, place of study, form of Sjogren's syndrome, studied population, study duration, prevalence of primary Sjogren, prevalence of secondary Sjogren, and overall prevalence of Sjogren's syndrome in the population and the gender groups.

Statistical analysis

We used the sample size and the variance of the studies to

combine them. We also used the Q Cochrane test and the I^2 index to assess the heterogeneity of the studies. The I^2 index has three levels (less than 25% for low heterogeneity, 25% to 75% for moderate heterogeneity, and more than 75% for substantial heterogeneity). Accordingly, we employed the random effects model (I^2 = 99.8%). We conducted the STATA 14 software for data analysis, and the significance level was $P<0.05$.

Results

We obtained 568 studies in the initial search. We investigated the titles and removed 195 duplicate studies. We examined the abstracts and excluded 17 studies with unavailable texts. Then, we examined the full texts and excluded 44 studies that did not report the necessary data, like the sample size or prevalence of Sjogren's syndrome. Next, we excluded 288 more studies based on the exclusion criteria. For this reason, we included 24 studies in the systematic review and meta-analysis (Figure 1).

This meta-analysis included 24 cohorts and cross-sectional studies between 1990 and 2023. The total number of participants was 21 349 (Table 1).

Findings showed that the worldwide prevalence of Sjogren's syndrome was (13% [95% CI: 10%, 16%]) (Figure 2). However, the prevalence of Sjogren's syndrome among females was (15% [95% CI: 4%, 26%]) (Figure 3).

In addition, the prevalence of primary Sjogren's syndrome was ((7% [95% CI: 5%, 9%]) and the prevalence of secondary Sjogren syndrome was (9% [95% CI: 6%, 13%]). Nevertheless, the population of some of the studies was the patients of both groups (a mixture of primary and secondary Sjogren) (Figures 4 and 5).

Subgroup analysis showed that the prevalence of Sjogren's syndrome among the age groups of 20-29, 30-39, 40-49, 50-59, 60-69, and 70-79 years was (31% [95% CI: 30%, 42%]), (4% [95% CI: 1%, 6%]), (7% [95% CI: 5%, 10%]), (24% [95% CI: 15%, 33%]), (22% [95% CI: 2%, 42%]), and (5% [95% CI: 1%, 9%]), respectively. In the 20–29 age group, we found only one study, and without considering that, the lowest and highest prevalence of Sjogren's syndrome was in the 30-39 and 50–59 age groups, respectively (Figure 6).

After categorizing based on the study types, we found that the global prevalence of Sjogren's syndrome was (14% [95% CI: 10%, 19%]) in the cohort studies and (10% [95% CI: 7%, 14%]) in the cross-sectional studies (Figure 7).

The meta-regression graph in Figure 8 shows that there is no significant statistical relationship between "the worldwide prevalence of Sjogren's syndrome" and "the sample size of the studies" (P = 0.319). In other words,

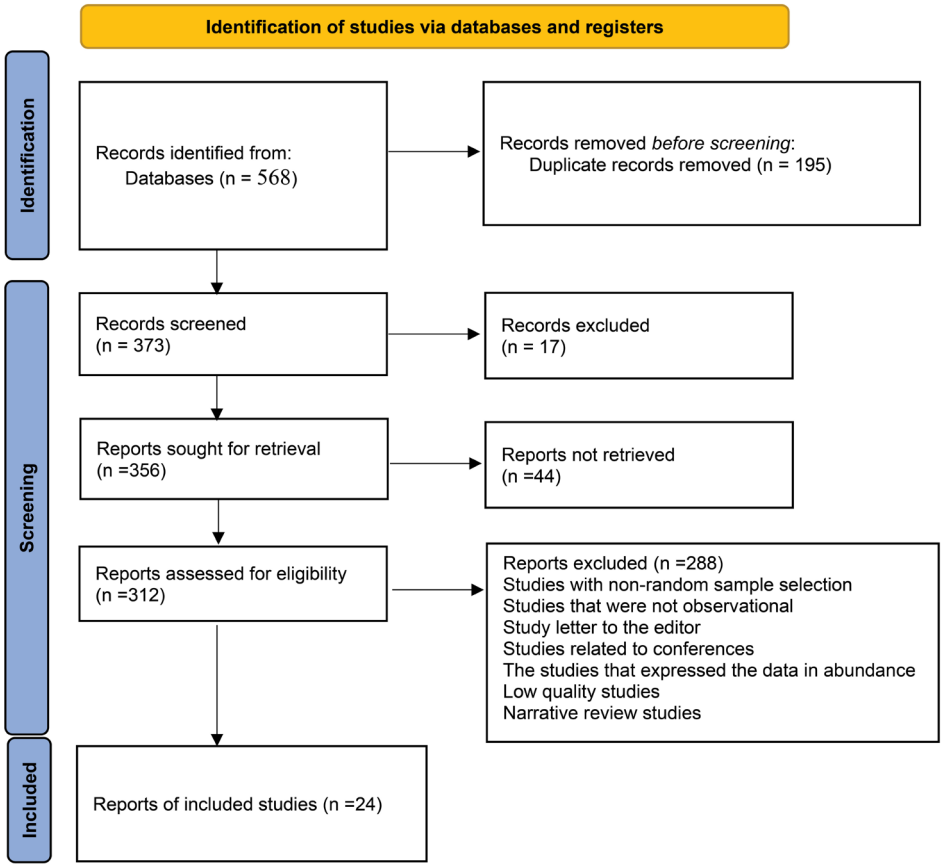

Figure 1. Flowchart of entering studies into the process of systematic review and meta-analysis.

Table 1. Characteristics of articles entered into the meta-analysis process

Author, year of publication	Country	Sample size	Age (year)	No. of female	No. of male	Period of study	Population	Type of Sjogren's syndrome
Gianordoli AP, 2023 (15)	Brazil	237	NR	NR	NR	between 2016 and 2018	Patients with systemic lupus erythematosus	Primary/Secondary
Dezsi AJ, 2023(16)	Hungary	1076	53.6	996	80	2008 to 2015	Patients with dry and burning mouth	Primary/Secondary
Can G, 2021(7)	Turkey	102	52.5	91	11	NR	Patients with sclerosis	Primary/Secondary
Harrold LR, 2020(17)	USA	24528	60.25	18846	5682	between 22 Apr 2010 and 28 Feb 2018	Patients with Rheumatoid arthritis	Primary/Secondary
Kim H, 2020(18)	Korea	827	57	732	NR	between May 20 and Jul 22, 2016	Patients with Rheumatoid Arthritis	Primary/Secondary
Lee YC, 2018 (19)	Korea	125	61.9	95	30	Patients with burning mouth symptoms	Patients with dry and burning mouth	Primary/Secondary
Sato T, 2018 (20)	Japan	40	37	28	12	between Jan 2005 and Aug 2016	General population	Primary
Santosh K, 2017 (21)	India	199	44	178	21	between Jan and Nov 2015	Patients with Rheumatoid arthritis	Secondary
Takizawa H, 2016 (22)	Japan	71	NR	NR	NR	between Apr 2010 and Dec 2014	Non-specific pleuritis on histopathology	Primary/Secondary
Yen JC, 2015 (23)	Taiwan	48704	49.8	34161	14543	2000 to 2008	Patients with dry eye	Primary/Secondary
Yen JC, 2015 (23)	Taiwan	128542	48.7	84918	43624	2000 to 2008	General population	Primary/Secondary
Valim V, 2013 (24)	Brazil	1205	36.2	614	591	2010	General population	Primary
Hernandez-Molina G, 2013 (25)	Canada	103	30.9	93	10	NR	Patients with systemic lupus erythematosus	Primary/Secondary
Kosrirukvongs P, 2012 (26)	Thailand	54	54.1	51	3	during Mar 2009-Sep 2010	Patients with Rheumatoid arthritis	Secondary
Haga HJ, 2012 (6)	Denmark	307	62.5	210	97	NR	Patients with Rheumatoid arthritis	Secondary
Zhang M, 2012 (27)	USA	327	60	NR	NR	NR	Patients with dry eye	Primary/Secondary
Yoshikawa K, 2012 (28)	Japan	265	77.9	168	97	from 2007 to 2010	Patients in a memory clinic	Primary
Haugen AJ, 2008 (29)	Norway	2864	71-74			1997–1999	General population	Primary
Kobak S, 2007 (30)	Turkey	70	42	14	56	between Jan 2002 and Nov 2003	Patients with ankylosing spondylitis	Primary/Secondary
Kabasakal Y, 2006 (4)	Turkey	831	37.7	831	NR	between Jul 2001 and Feb 2002	General population	Primary
Sanchez-Guerrero J, 2005 (31)	Mexico	300	42.8	238	62	NR	Ambulatory patients	Primary/Secondary
Loustaud-Ratti VE, 2001 (5)	France	45	49.6	22	23	NR	Patients with Chronic Hepatitis C Virus Infection	Primary
Thomas E, 1998 (32)	UK	341	18-75	NR	NR	NR	General population	Primary/Secondary
Miro J, 1990 (33)	Spain	64	29.1	NR	NR	NR	Patients with sclerosis	Primary
Coll J, 1987 (34)	Spain	122	52	108	14	NR	Autoimmune diseases	Primary/Secondary

NR: Not reported.

we did not observe the studies with a larger sample size to report a higher overall prevalence of Sjogren's syndrome or the studies with a smaller sample size to report a lower overall prevalence of Sjogren's syndrome.

Likewise, Figure 9 shows no significant statistical relationship between "the worldwide prevalence of Sjogren's syndrome" and "the publication year of the studies" ($P = 0.223$). Particularly, the worldwide prevalence of Sjogren's syndrome in the last 33 years does not show a downward trend.

Discussion

The results of combining the studies using the random effects model showed that 13 out of 100 people worldwide are affected by Sjogren's syndrome, with the highest risk for females and those in the 50–59 age group. This high prevalence is very concerning due to the aging process in most societies.

In the Fernández-Ávila Colombian cross-sectional study, the prevalence of Sjogren's syndrome in people aged more than 18 years was 0.12%; 82% of them were women, and the highest prevalence was in the 60-69 year age group (35). Another cross-sectional study conducted by Maldini and colleagues in a multiracial region of France reported the prevalence of primary Sjogren's syndrome to be 1.52 in every 10 000 adults (36). The results of these studies

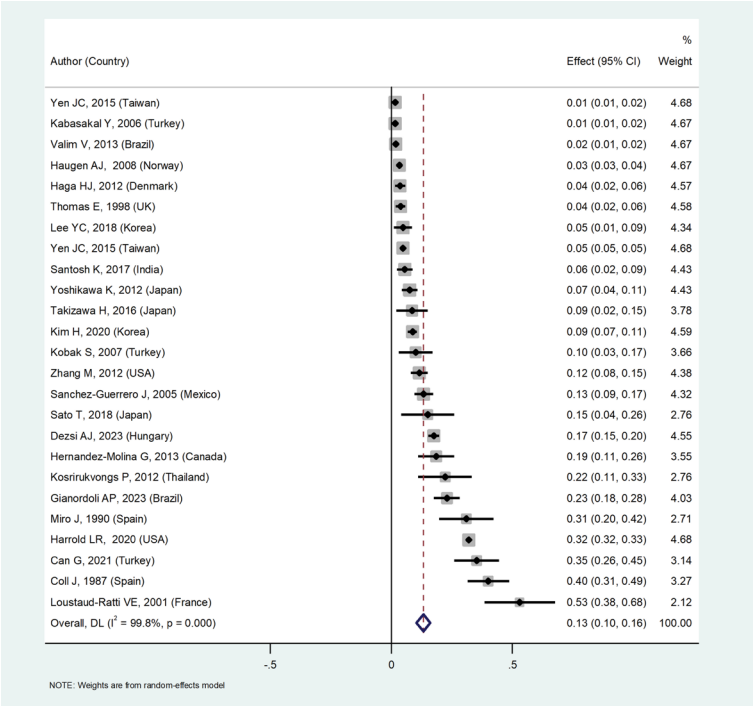

Figure 2. Forest diagram related to the overall prevalence of Sjogren's syndrome in the world and its 95% confidence interval.

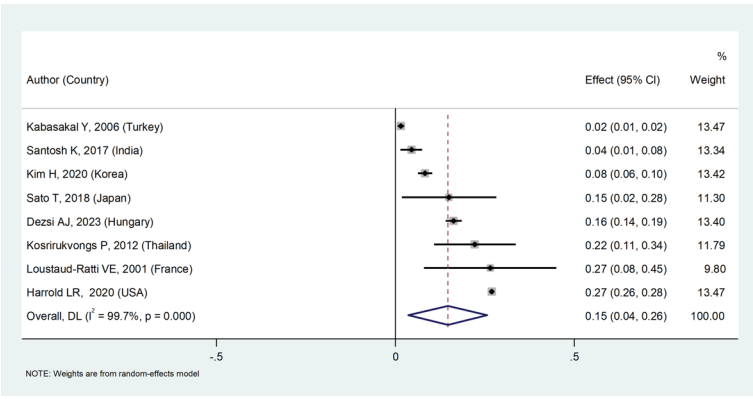

Figure 3. Forest diagram related to the prevalence of Sjogren's syndrome in female and its 95% confidence interval.

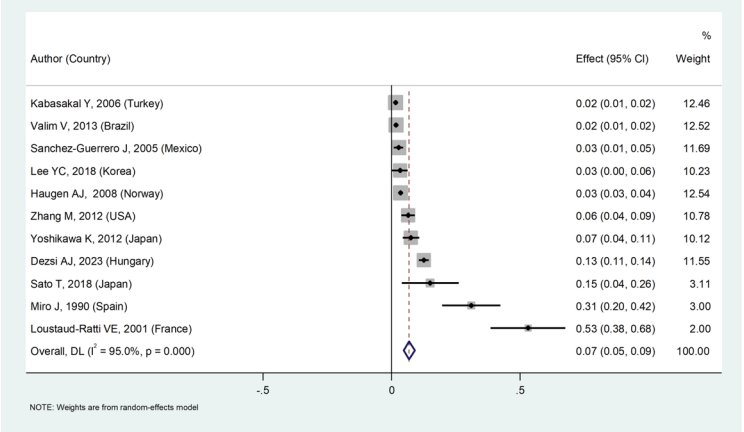

Figure 4. Forest diagram related to the overall prevalence of primary Sjogren's syndrome in the world and its 95% confidence interval.

are discordant with ours because they have reported a low prevalence of the overall Sjogren's syndrome and the primary Sjogren's syndrome. However, our study type, race, comorbidities, and sample size differ from the other studies mentioned, which could have caused the difference in their conclusions.

Qin and colleagues' meta-analysis of the prevalence rate (PRs) and the incidence rate (IRs) reported that the combined incidence rate of primary Sjogren's syndrome was 6.92 in 100 000 people per year, and the overall prevalence was 60.82 in 100 000. The female-male ratio in the prevalence data was 10.72 (37). Thurtle and colleagues' review study suggested that the primary Sjogren's syndrome had the highest prevalence and incidence in women and those with higher ages (more incidence in 65 years, more prevalence in 75 years) (38). Deng and colleagues meta-analysis included 17 studies and reported the prevalence of Sjogren's syndrome in patients with primary biliary cholangitis from 3.5% to 73% (35% combined) (39). On the contrary, a meta-analysis by Alani et al investigated the epidemiology of secondary Sjogren's syndrome in relation to rheumatoid arthritis, systemic lupus erythematosus, scleroderma, and dermatomyositis and reported that the combined prevalence of secondary Sjogren's syndrome

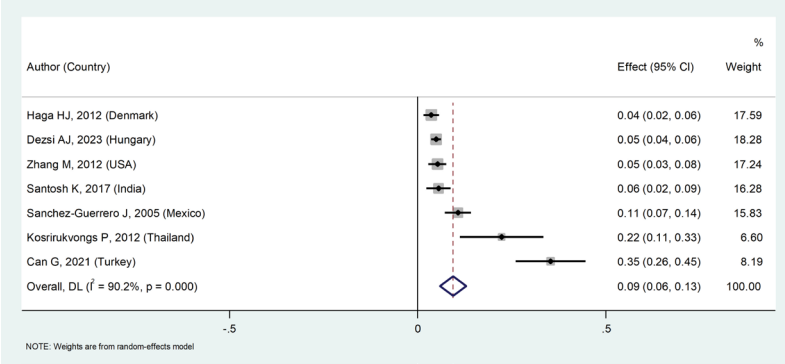

Figure 5. Forest diagram related to the overall prevalence of secondary Sjogren's syndrome in the world and its 95% confidence interval.

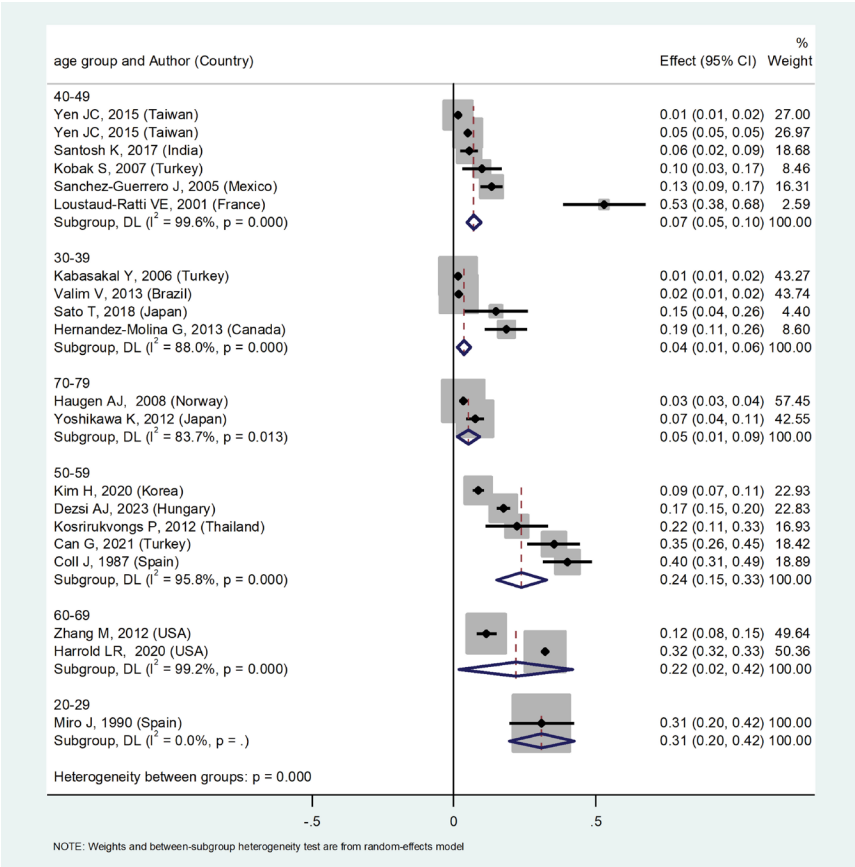

Figure 6. Forest diagram related to the overall prevalence of Sjogren's syndrome in the world and its 95% confidence interval by age group.

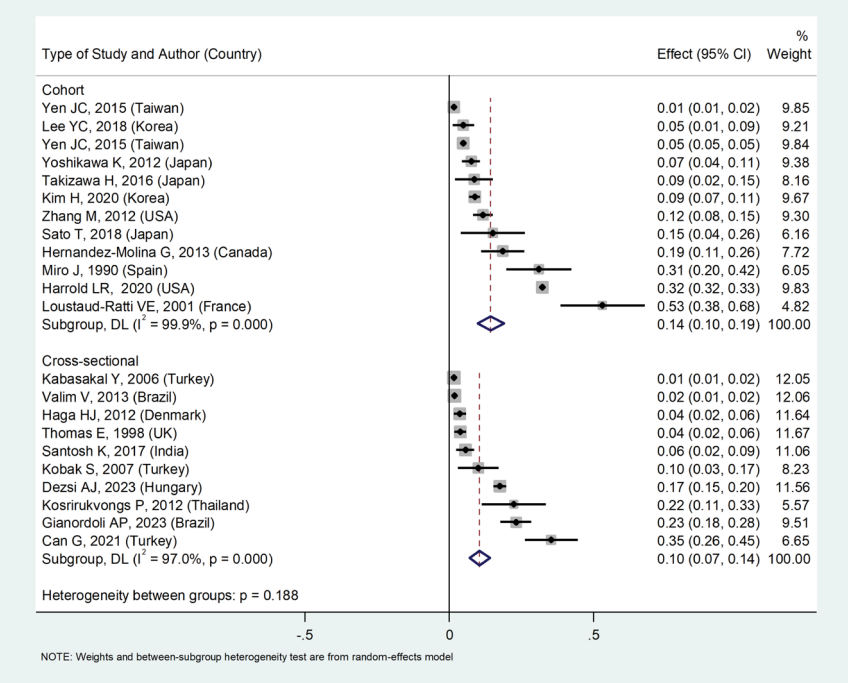

Figure 7. Forest diagram related to the overall prevalence of Sjogren's syndrome in the world and its 95% confidence interval by type of studies.

linked to rheumatoid arthritis was 19.5% and the combined prevalence of secondary Sjogren's syndrome linked to systemic lupus erythematosus was 13.96%. The female-male ratio of secondary Sjogren's syndrome in rheumatoid arthritis and systemic lupus erythematosus populations was 14.7% and 16.82%, respectively (11). The results of that study were in accordance with the present study and showed the highest prevalence of Sjogren's syndrome in women and at higher ages. Furthermore, in our study, the prevalence of Sjogren's syndrome in the female group was higher than that of Sjogren's syndrome.

According to Almutairi and colleagues' meta-analysis, which included 67 studies, the worldwide prevalence of rheumatoid arthritis was 0.46% (40). A South African meta-analysis by Germano and colleagues included 25 studies and reported a 0.48% overall prevalence of rheumatoid arthritis (41). Fatoye et al conducted a meta-analysis on low- and middle-income countries and reported a varying prevalence of systemic lupus erythematosus, ranging from 3.2 to 159 in 100 000 (42). Tian et al investigated 112 studies and estimated that the worldwide incidence of systemic lupus erythematosus and the newly diagnosed population was 5.14 in 100 000 people each year and 0.4 million patients per year, respectively (43). Based on the similarity of these studies with the present study, we can conclude that the worldwide prevalence of Sjogren's syndrome is higher than the combined prevalence of rheumatoid arthritis and systemic lupus erythematosus.

Conclusion

About 13 individuals of every 100 people worldwide are affected by Sjogren's syndrome, and the prevalence

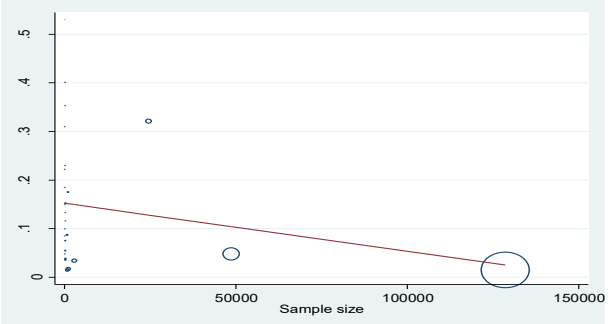

Figure 8. Meta-regression plot of the relationship between "overall prevalence of Sjogren's syndrome in the world" and the sample size of studies.

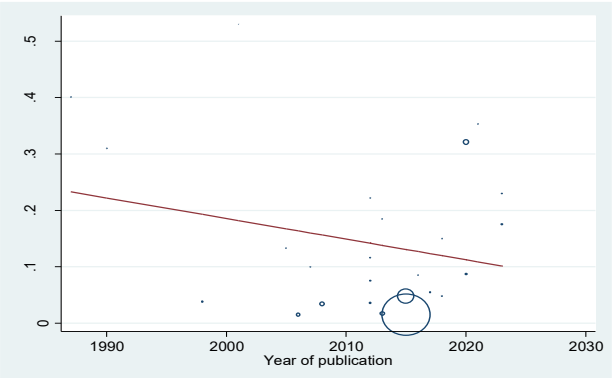

Figure 9. Meta-regression plot of the relationship between "overall prevalence of Sjogren's syndrome in the world" and year of publication of studies.

of Sjogren's syndrome is slightly higher in the female population than the overall prevalence, with 15 out of every 100 women affected. Furthermore, the 50–59 age group has the highest risk for this disease; hence their risk is twice the worldwide prevalence of Sjogren's syndrome. Considering the high prevalence, the adverse effects, and the costs of this disease for the patient and society, we suggest that measures should be taken to decrease the prevalence of Sjogren's disease.

Limitations of the study

Most of the studies reported the overall prevalence of Sjogren's syndrome and did not mention the prevalence of primary and secondary Sjogren's syndrome. Most studies did not report the prevalence of Sjogren's syndrome in the male population. The full text of some studies was not accessible. We did not perform the subgroup analysis based on the comorbidities because of the high variety of diseases and the low number of investigated studies. We did not perform the subgroup analysis based on the region because of the low number of investigated studies and the high number of assessed countries. Hence, we cannot suggest the county or the race with the highest prevalence of Sjogren's syndrome.

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Authors' contribution

Conceptualization: Jalal Rezaei and Roya Azouji.
Data curation: Arash Neshati and Amirhosein Abareghi.
Formal analysis: Mohammad Shirvani and Sina Khatib.
Investigation: Shahriar Barkhordari and Farangis Yazdanjou.
Methodology: Mohammad Shirvani.
Project management: Jalal Rezaei.
Resources: All authors.
Supervision: Shahriar Barkhordari.
Validation: Rasoul Jafari Arismani.
Visualization: Rasoul Jafari Arismani.
Writing–original draft: All authors.
Writing–reviewing and editing: All authors.

Conflicts of interest

There are no competing interests.

Ethical issues

This investigation has been compiled based on the PRISMA checklist, and its protocol was registered on the PROSPERO (International Prospective Register of Systematic Reviews) (ID: CRD42024513783) and Research Registry websites (Unique Identifying Number (UIN) reviewregistry1793). Besides, the authors have completely observed ethical issues (including plagiarism, data fabrication, and double publication).

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