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The risk of breast cancer in patients with Sjogren's syndrome; a systematic review and meta-analysis

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Abstract

Introduction: Breast cancer represents the most prevalent solid tumor in people with Sjögren's syndrome. Consequently, this paper aimed to evaluate the association between Sjögren's syndrome and the breast cancer risk.

Materials and Methods: The paper protocol was designed and executed in accordance with the PRISMA reporting guidelines. A comprehensive systematic search was conducted across the Cochrane Library, Web of Science, Scopus, PubMed, and Embase databases, supplemented by Google Scholar. The literature search was updated through April 25, 2026. All statistical analyses were performed using STATA version 14.

Results: In 16 studies, no significant association was found between Sjögren's syndrome and breast cancer risk [(SIR: 1.05, 95% CI: 0.75, 1.46), (HR: 0.79, 95% CI: 0.45, 1.40), (OR: 0.98, 95% CI: 0.86, 1.12)]. Additionally, no statistically significant link was observed between Sjögren's syndrome and breast cancer among women aged 50 to 54 (SIR: 0.96, 95% CI: 0.63, 1.45), 55 to 60 (SIR: 1.29, 95% CI: 0.83, 2.01), and older than 60 (SIR: 0.94, 95% CI: 0.79, 1.11), in cohorts (SIR: 0.98, 95% CI: 0.74, 1.30), and in case-controls (SIR: 0.98, 95% CI: 0.86, 1.12). Notably, Sjögren's syndrome was associated with a decreased risk of breast cancer in Sweden (SIR: 0.46, 95% CI: 0.32, 0.66) and France (SIR: 0.60, 95% CI: 0.49, 0.74); an increased risk was identified in Argentina (SIR: 3.76, 95% CI: 1.25, 11.33), and Turkey (SIR: 2.55, 95% CI: 1.50, 4.35).

Conclusion: Overall, no statistically significant correlation was found between Sjögren's syndrome and breast cancer risk. However, it was associated with a decreased risk in Sweden and France, while the correlation was positive in Turkey and Argentina.

Registration: This study has been compiled based on the PRISMA checklist, and its protocol was registered on the PROSPERO (CRD420261383821).

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Introduction

The prevalence of Sjögren's syndrome is about 0.2% to 2.7% (1). Sjögren's syndrome typically exhibits a bimodal age distribution, with the first peak occurring in the 20s and the second peak in the mid-50s (2). According to the American College of Rheumatology classification criteria, Sjögren's syndrome is categorized into two types: primary Sjögren's syndrome (3), which occurs without another underlying rheumatic disease, and secondary Sjögren's syndrome, which is associated with rheumatic conditions such as systemic lupus erythematosus (4), rheumatoid arthritis, or systemic sclerosis (5). Primary Sjögren's syndrome is the most prevalent form of primary Sjögren's syndrome and it is a common systemic autoimmune disease characterized by dryness of exocrine glands, such as the lacrimal and salivary glands (6). The gender distribution in primary Sjögren's syndrome patients is markedly skewed, with females accounting for over 90% of cases (7,8).

While Sjögren's syndrome is a significant risk for hematologic tumors, its correlation with solid cancer remains poorly defined (9). A cross-sectional study identified breast cancer as the most prevalent solid malignancy among individuals with Sjögren's syndrome (10). As of 2022, breast cancer was ranked as the second most common cancer in the world and the fourth leading cause of cancer-related deaths, with one in eight cancer diagnoses being breast cancer. (11). Approximately 2.31 million new breast cancer cases were reported global in 2022, accounting for 11.6% of all tumor incidences (11,12). Furthermore, breast cancer is the most prevalent neoplasm and the primary cause of cancer-related death among women (13). Therefore, elucidating the association between Sjögren's syndrome and breast cancer risk in women is of significant importance.

Some studies indicate that Sjögren's syndrome increases breast cancer risk (14,15), while others suggest no statistically significant relationship between them (16,17) or even that Sjögren's syndrome

Key point

In a systematic review and meta-analysis, we found no statistically significant correlation between Sjogren's syndrome and breast cancer risk. However, it was associated with a decreased risk in Sweden and France, while the correlation was positive in Turkey and Argentina.

decreases breast cancer risk (18,19). Given these substantial inconsistencies among the findings of previously published studies, the goal of the present paper was to investigate the association between Sjögren's syndrome and breast cancer risk in women. Therefore, our systematic review and meta-analysis was conducted to synthesize the conflicting results of earlier studies and provide a comprehensive conclusion.

Materials and Methods

Study design

The protocol of this study was designed based on PRISMA (20) and registered in the PROSPERO website.

Search strategy

A comprehensive search was executed in the Cochrane Library, Scopus, Web of Science, Embase, PubMed, and Google Scholar to identify relevant literature, using standard keywords and related MeSH terms, with no time or language restrictions (up to April 25, 2026). In an advanced search, Boolean logic operators (AND, OR, and NOT) were applied to combine the keywords. Furthermore, the reference lists of selected articles were manually searched (see Supplementary file 1). For example, the search strategy used in Scopus followed: (TITLE-ABS-KEY (Breast Neoplasms OR Breast Cancer OR Breast Carcinoma) AND TITLE-ABS-KEY (Sjogren's Syndrome OR Sicca Syndrome))

PECO framework

P (population): Studies investigating the association between Sjögren's syndrome and breast cancer risk; E (exposure): Suffering from Sjögren's syndrome; C (comparison): No Sjögren's syndrome; O (outcome): Breast cancer risk.

Inclusion and exclusion criteria

Articles that evaluated the association between Sjögren's syndrome and breast cancer risk were included. Exclusion criteria encompassed meta-analyses, studies lacking sufficient data for analysis, studies investigating the association between Sjögren's syndrome and the risk of all types of tumors without reporting breast cancer separately, studies whose full texts were unavailable even after emailing the authors, studies investigating the association between Sjögren's syndrome and autoimmune diseases without referring to breast cancer separately, duplicate content or studies indexed in more than one database, studies investigating the association between Sjögren's syndrome and other women-specific (e.g., ovarian, uterine, or breast) cancers without referring to breast cancer independently, studies with poor qualitative assessment quality, and review articles.

Qualitative assessment

Two researchers assessed the methodological quality of the original articles using Newcastle-Ottawa scale. Except for one item, this scale awards at most one star per question, yielding overall scores from 0 to 10, with scores below 5 designating low-quality studies (21).

Data extraction

Two independent researchers extracted the data using SPSS software version 19, including country, study design, author name, year, mean age, and the association between Sjögren's syndrome and breast cancer with its upper and lower limits.

Statistical analysis

The logarithms of hazard ratio (HR), odds ratio (OR), and standardized incidence ratio (SIR) were calculated to synthesize the studies. The I^2 statistic was used to assess the heterogeneity of the studies. Accordingly, in situations where the heterogeneity between articles was statistically low, the fixed effects model was conducted, and in situations where the heterogeneity between articles was statistically moderate to high, the random effects model was employed. Data were analyzed statistically with STATA 14 at a significance level of $P < 0.05$ for all tests.

Results

From an initial pool of 233 articles, 148 duplicates, 7 articles due to a deficient of abstracts or inaccessible full texts, 43 studies lacking essential data for analysis, and 9 others due to the exclusion criteria were excluded. Finally, a systematic review and meta-analysis were performed on the remaining 16 studies (Figure 1).

In this meta-analysis, 16 observational studies (including 14 cohort studies and 2 case-control studies) were reviewed, which evaluated a total of 58,342 people (Table 1).

No statistically significant correlation was found between Sjögren's syndrome and breast cancer [(SIR: 1.05, 95% CI: 0.75, 1.46), (HR: 0.79, 95% CI: 0.45, 1.40), (OR: 0.98, 95% CI: 0.86, 1.12)] (Figure 2).

Sjögren's syndrome decreased breast cancer risk in Sweden (SIR: 0.46, 95% CI: 0.32, 0.66) and France (SIR: 0.60, 95% CI: 0.49, 0.74) and increased it in Turkey (SIR: 2.55, 95% CI: 1.50, 4.35) and Argentina (SIR: 3.76, 95% CI: 1.25, 11.33). However, no significant link between Sjögren's syndrome and breast cancer risk was found in Italy (SIR: 0.65, 95% CI: 0.37, 1.14), Spain (SIR: 0.89, 95% CI: 0.53, 1.50), the USA (SIR: 0.98, 95% CI: 0.86, 1.12), Taiwan and China (SIR: 1.11, 95% CI: 0.94, 1.31), and Lithuania (SIR: 1.27, 95% CI: 0.41, 3.93) (Figure 3).

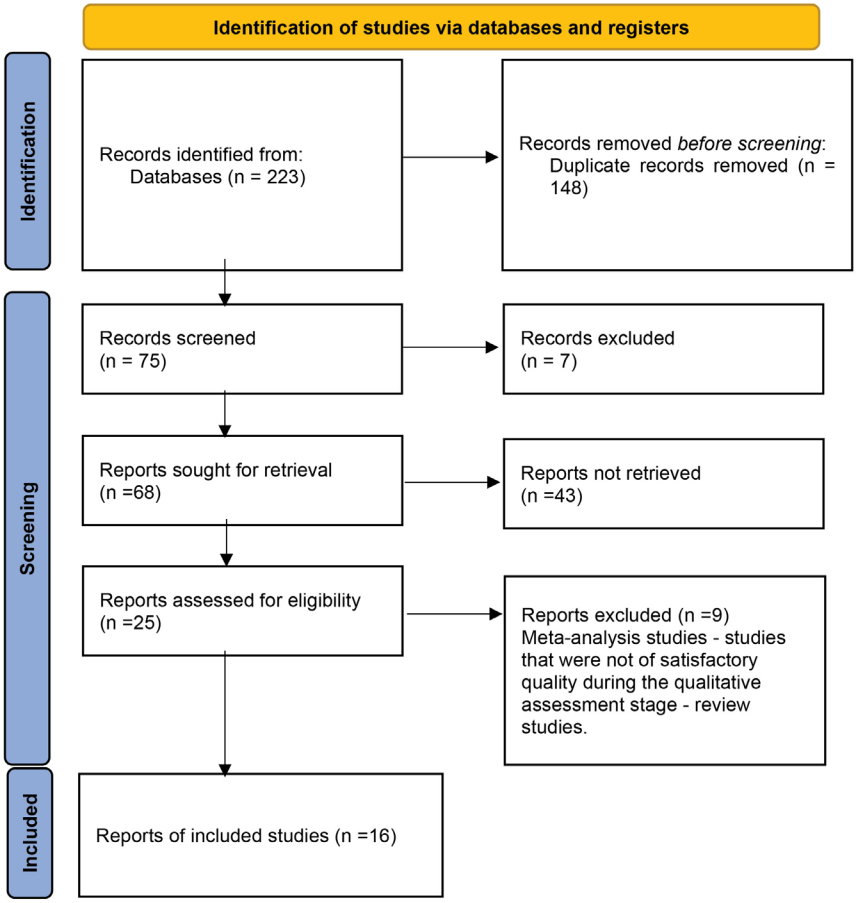

Figure 1. PRISMA flow diagram of the studies included.

Table 1. The important data from the articles under review

First author, year	Index	Country	Type of study	Duration of study	Sample size	Mean age (year)	Risk of breast cancer	Low limit	Up limit
Sjostrom B, 2026 (18)	SIR	Sweden	Cohort	from 1958 to 2019	446	53.4	0.46	0.24	0.69
Tuzcu TU, 2026 (14)	SIR	Turkey	Cohort	NR	323	56	3.8	1.5	7.9
Tsai JJ, 2025 (22)	HR	Taiwan, China	Cohort	from 1 Jan 2018 to 31 Dec 2022	5103	55.9	1.07	0.76	1.52
Denizhan TK, 2025 (23)	SIR	Turkey	Cohort	between Jan 2011 and Feb 2023	303	54	1.85	0.68	4.10
Jonusiene G, 2025 (16)	SIR	Lithuania	Cohort	between 1 Jan 2012 and 31 Dec 2019	309	59.71	1.27	0.41	3.92
Treppo E, 2022 (24)	SIR	Italy	Cohort	from 2002 to 2017	2504	57	0.65	0.35	1.08
Weng MY, 2012 (25)	SIR	Taiwan, China	Cohort	from 2000 to 2008	6911	53	0.99	0.7	1.36
Gadalla SM, 2009 (26)	OR	USA	Case-control	1993–2002	374	67-99	1.06	0.85	1.32
Aslan B, 2022 (27)	SIR	Turkey	Cohort	between Jan 2004 and Dec 2018	430	58.3	2.08	0.41	3.74
Goulabchand R, 2021 (28)	HR	French	Cohort	from 2011 to 2018	25661	NR	0.6	0.49	0.74
Brom M, 2019 (15)	SIR	Argentina	Cohort	2000-2015	157	57.8	3.76	1.04	9.45
Schairer C, 2018 (29)	OR	USA	Case–control	1992–2011	721	76	0.94	0.79	1.11
Brito-Zeron P, 2017 (30)	SIR	Spain	Cohort	2005-2016	1300	54.8	0.89	0.53	1.51
Yu KH, 2016 (17)	SIR	Taiwan, China	Cohort	from 1997 to 2010	11998	53.54	1.18	0.94	1.48
Hemminki K, 2012 (19)	SIR	Sweden	Cohort	up to year 2008	1516	NR	0.46	0.26	0.75
Theander E, 2006 (31)	SIR	Sweden	Cohort	from 1984 until 31 Dec 2002	286	56	0.51	0.1	1.48

NR: Not reported; HR: Hazard ratio; OR: Odds ratio; SIR: Standardized incidence ratios.

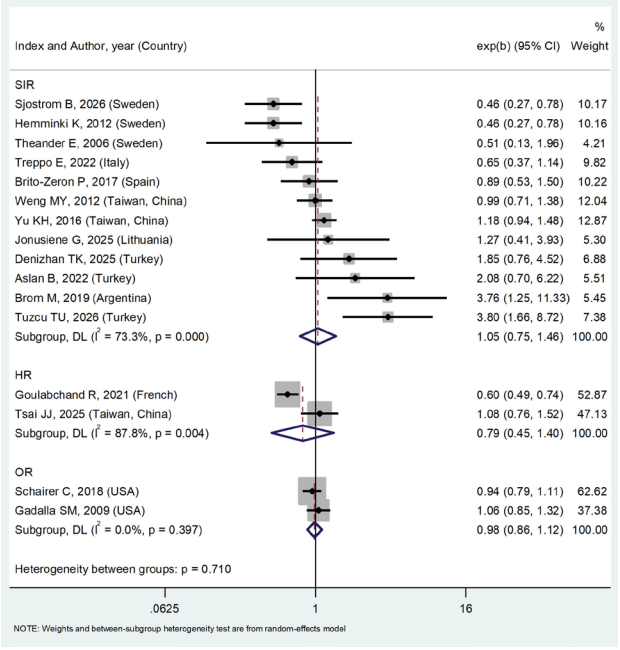

Figure 2. Forest plot related to the association between Sjogren's syndrome and risk of breast cancer.

Furthermore, no statistically significant correlation was found between Sjögren's syndrome and breast cancer risk in either cohort (SIR: 0.98, 95% CI: 0.74, 1.30) or case-control studies (SIR: 0.98, 95% CI: 0.86, 1.12) (Figure 4).

No statistically significant link between Sjögren's syndrome and breast cancer risk was found in women aged 50 to 54 (SIR: 0.96, 95% CI: 0.63, 1.45), 55 to 60 (SIR: 1.29, 95% CI: 0.83, 2.01), and older than 60 (SIR: 0.94, 95% CI: 0.79, 1.11) (Figure 5).

Meta-regression indicated that the association between Sjögren's syndrome and breast cancer risk was not influenced by sample sizes of preliminary studies (P = 0.350). In other words, the sample sizes of included studies had no impact on the association between Sjögren's syndrome and breast cancer risk (Figure 6).

The test for publication bias was not statistically significant (P = 0.441). In other words, there was no statistically significant evidence indicating publication bias in the included articles, which denotes a flawless literature search and probably no study with insignificant or negative results was missed, proving that the search was comprehensive (Figure 7).

Sensitivity analysis revealed that the articles conducted by Tuzcu et al (14) and Sjöström et al (18) had substantially the greatest influence on the final findings of the present meta-analysis, such that, unlike the other studies, deleting either of them would result in significant change in the final results (Figure 8).

Discussion

In the present meta-analysis, no overall statistically significant link was found between Sjögren's syndrome and breast cancer risk. However, in some regions (Sweden, France, Turkey, and Argentina) the association was significant.

In a meta-analysis conducted by Liang et al to evaluate the correlation between primary Sjögren's syndrome and malignancy risk, compared to the general population,

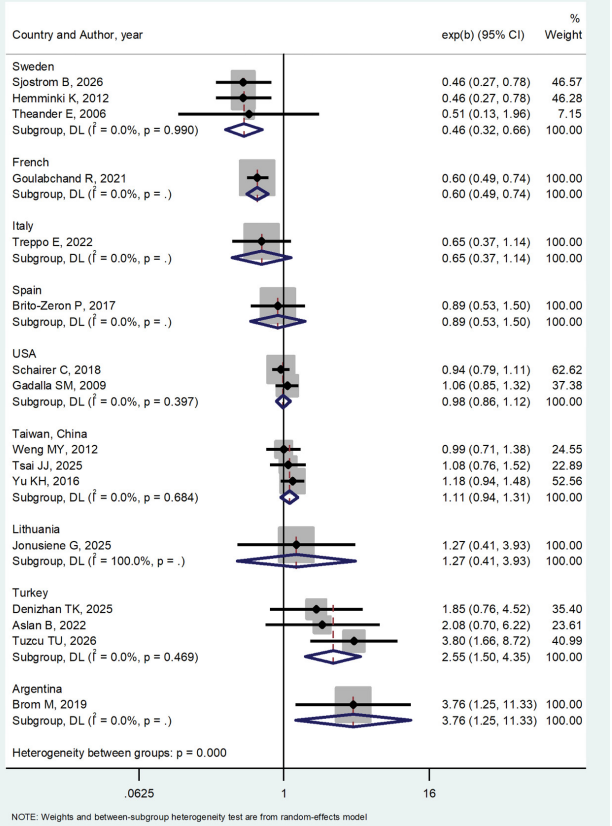

Figure 3. Forest plot related to the association between Sjogren's syndrome and risk of breast cancer by place.

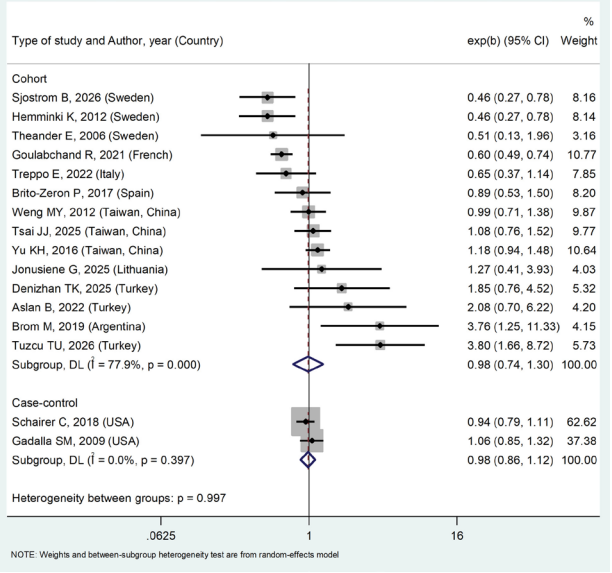

Figure 4. Forest plot related to the association between Sjogren's syndrome and risk of breast cancer by type of study.

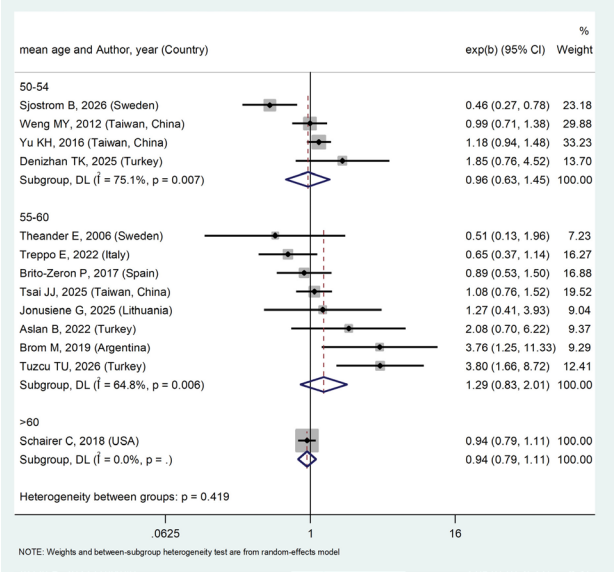

Figure 5. Forest plot related to the association between Sjogren's syndrome and risk of breast cancer by age.

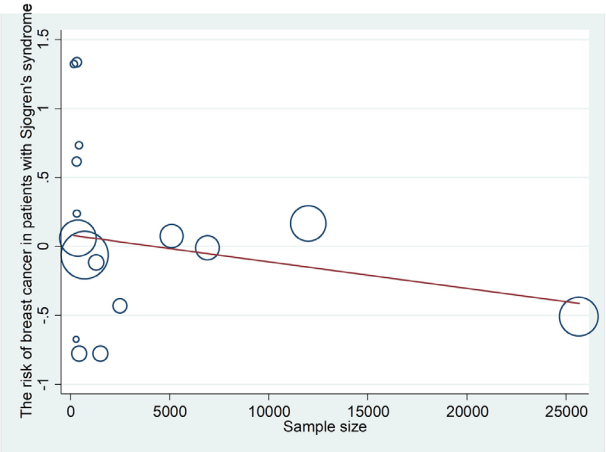

Figure 6. Meta-regression showing the association between Sjogren's syndrome and risk of breast cancer with sample size.

primary Sjögren's syndrome patients were found to be at higher risk (RR: 1.53, 95% CI: 1.17, 1.88), while no statistically significant association between primary Sjögren's syndrome and breast cancer risk was found (RR: 0.67, 95% CI: 0.27, 1.06) (32). In another meta-analysis conducted by Deng et al, primary Sjögren's syndrome was not associated with breast cancer risk (SIR: 0.92, 95% CI: 0.66, 1.29) (33). Previously, Zhong et al conducted a meta-analysis to investigate the association between primary Sjögren's syndrome and malignancy. Their study showed that primary Sjögren's syndrome was associated with all types of malignancies (SIR: 2.17, 95% CI: 1.57, 3.00) and hematologic malignancies (SIR: 11.55, 95% CI: 4.32, 30.90), but the association between primary Sjögren's syndrome and breast cancer risk (SIR: 0.98, 95% CI: 0.55, 1.72) was not significant (34). The findings of our meta-analysis are consistent with previous meta-analyses. In fact, earlier studies confirm no statistically significant

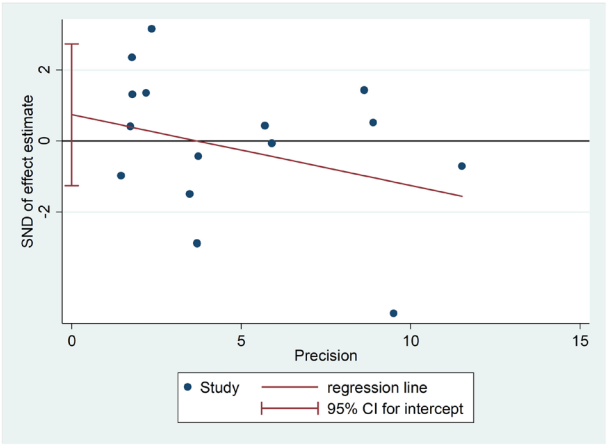

Figure 7. Publication bias.

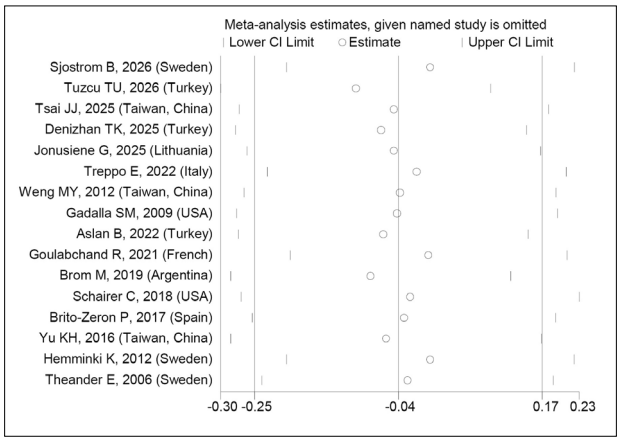

Figure 8. Sensitivity analysis.

association between Sjögren's syndrome and breast cancer risk. The consistency between multiple studies with different populations reinforces our results.

In a Mendelian paper conducted by Lu et al, no statistically significant link between Sjögren's syndrome and breast cancer risk was found (OR: 1, 95% CI: 0.99, 1) (35). In Tsai et al cohort study, Sjögren's syndrome was not significantly associated with breast cancer risk (HR: 1.07, 95% CI: 0.76, 1.52) (22). In the present meta-analysis, by pooling the results of cohort studies, we concluded that there is no statistically significant association between Sjögren's syndrome and breast cancer risk.

Chen et al cohort study on primary Sjögren's syndrome patients indicated that primary Sjögren's syndrome patients had higher breast cancer prevalence and incidence (36). According to a cohort study conducted by Rusinovich-Lovgach et al to assess breast cancer risk in Sjögren's syndrome patients, an overall increased risk of tumor was found (SIR: 1.68, 95% CI: 1.68, 1.69), with considerably higher risk of hematologic malignancies (SIR: 3.55, 95% CI: 3.54, 6.56) and moderately higher risk of solid tumors (SIR: 1.54, 95% CI: 1.53, 1.55) (37). In the Jonušienė et al cohort study to investigate cancer risk in Sjögren's syndrome patients, higher risk of all types

of cancers was found (SIR: 2.11, 95% CI: 1.44, 3.07) (16). Denizhan et al cohort study found that Sjögren's syndrome patients, compared to the general population, had a higher risk of solid (SIR: 2.25, 95% CI: 1.51, 3.22) and hematologic (SIR: 7.22, 95% CI: 2.93, 5.04) malignancies (23). Contrary to the present meta-analysis, such cohort studies identified Sjögren's syndrome as an independent cancer risk factor. However, in cases of discrepancy between individual preliminary studies and a comprehensive meta-analysis, usually a pooled estimate that is based on the totality of available evidence should be considered more reliable. In consequence, the present study has higher generalizability, as it synthesizes previous studies and includes a greater sample size.

In the Mendelian study conducted by Zhang et al, which aimed to assess the association between autoimmune diseases and breast cancer, Sjögren's syndrome was found to decrease breast cancer risk (OR: 0.96, 95% CI: 0.93, 0.99) (38). According to the Sjöström et al cohort study to compare the incidence of cancer before and after primary Sjögren's syndrome diagnosis, cancer incidence considerably decreased both before and after primary Sjögren's syndrome diagnosis, with a more apparent decrease in breast cancer incidences (SIR: 0.46, 95% CI: 0.24, 0.69) (18). While previously mentioned studies believed Sjögren's syndrome decreased breast cancer risk, the present meta-analysis concludes that neither positive nor negative significant association exists between Sjögren's syndrome and breast cancer risk. Therefore, the negative association could be produced only in certain subgroups, which was weakened in the pooled analysis.

Conclusion

Overall, there was no statistically significant association between Sjögren's syndrome and breast cancer risk. However, Sjögren's syndrome was found to decrease breast cancer risk in Sweden (54%) and France (40%). In contrast, Sjögren's syndrome was associated with increased breast cancer risk in Turkey and Argentina (2.55 and 3.76 fold higher than the general population, respectively).

Limitations of the study

1. No subgroup analysis based on Sjögren's syndrome type (primary and secondary) was performed, as some studies had not identified the Sjögren's syndrome type.
2. In the preliminary studies included in the present meta-analysis, no secondary outcome was mentioned besides the primary one (breast cancer risk).
3. The number of relevant case-control studies was low.

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Authors' contribution

Conceptualization: Shadi Botshekan and Azadeh Souzani.
Data curation: Shadi Botshekan and Azadeh Souzani.
Formal analysis: Mansour Salesi and Shadi Botshekan.
Investigation: Mansour Salesi and Azam Omidi.
Methodology: Mansour Salesi and Azam Omidi.
Project administration: Azadeh Souzani and Shadi Botshekan.
Supervision: All authors.
Validation: Azadeh Souzani and Shadi Botshekan.
Visualization: Azam Omidi and Shadi Botshekan.
Writing–original draft: All authors.
Writing–review and editing: All authors.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

This study has been compiled based on the PRISMA checklist, and its protocol was registered on the PROSPERO website (ID: CRD420261383821). Besides, ethical issues (including plagiarism, data fabrication, and double publication) have been completely observed by the authors.

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None.

Supplementary files

Supplementary file 1. Search strategies used in databases.

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