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WOMEN, IMMUNOLOGY, AND THERAPY: A BIBLIOMETRIC ANALYSIS OF ADVERSE DRUG EFFECTS IN THE SCIENTIFIC LITERATURE

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ABSTRACT:

In recent decades, the development of immunotherapies has profoundly transformed the treatment of autoimmune, infectious, oncological, and chronic diseases. However, numerous studies agree that knowledge regarding the adverse effects of these pharmacological treatments exhibits significant gaps, especially when analyzed from a sex-differentiated perspective. Women, due to their unique immunological, endocrine, and reproductive physiology, not only present a higher prevalence of autoimmune diseases but also demonstrate distinct immunopharmacological responses, which entail an increased risk of unforeseen or underreported adverse effects. Therefore, the present study aims to address the following research question: Does a network analysis of author-defined terms allow identification of the challenges related to adverse drug effects in women within the field of immunology? To answer this question, a bibliometric analysis was conducted using a corpus composed of publications from journals ranked in the Q1 quartile of the two main databases, Scopus and Web of Science, comprising a total of 548 articles. The results allowed the identification of four main clusters concentrating the conceptual terms defined by the authors: Cluster 1 Immunoregulation and reproductive therapies in women with immunological dysfunction; Cluster 2 Oncological immunotherapy and immune-mediated adverse events with metabolic impact; Cluster 3 Vaccines, HIV, and maternal-infant immunological health in vulnerable contexts; and Cluster 4 Biological therapies and immunometabolic and perinatal impact in women with chronic diseases. These findings contribute to the scientific production on this topic, opening new avenues for research that should be further explored through quantitative studies such as factor analysis and structural equation modeling.

Keywords: Women, immunology, therapy, bibliometric adverse drug effects, Python.

INTRODUCTION

The relationship between biological sex, immunology, and pharmacotherapy represents a field of growing interest in the biomedical literature. Women, in particular, exhibit unique immunological characteristics that significantly influence the onset and progression of adverse effects induced by various pharmacological treatments. These immunological differences are not anecdotal but rather the result of a complex biological framework modulated by sex hormones, genetic and epigenetic factors, and differential expression of immune receptors in key tissues [1].

Historically, medical research has been characterized by the underrepresentation of women in clinical trials, which has limited a comprehensive understanding of their immunological responses to drugs and vaccines. This bias has led to significant clinical consequences, such as the absence of specific protocols to prevent adverse reactions in pregnant or lactating women, particularly those living with autoimmune diseases [2]. For example, in a global cohort study on COVID-19 vaccination, adverse events were found to be significantly more frequent in pregnant women with autoimmune diseases compared to non-pregnant women with the same conditions (45% vs. 26%, $p = 0.01$) [2]. Furthermore, the post-vaccination relapse rate was 17.5% in pregnant women with autoimmune diseases, leading to adjustments in immunosuppressive therapy in a considerable proportion of these patients [2].

Immunologically, women exhibit higher helper T cell activity, increased antibody production, and a more robust inflammatory response factors that enhance their susceptibility to developing autoimmune diseases but also elevate their reactivity to vaccines and immunotherapies [3]. In this regard, a retrospective study of melanoma

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patients treated with immune checkpoint inhibitors (anti-PD-1) demonstrated that the presence of thyroid autoantibodies in women was closely associated with thyroid dysfunction during treatment, with a direct correlation between baseline seropositivity and the onset of adverse effects [3]. All women with thyroid autoantibodies at baseline developed thyroid dysfunction following immunotherapy, whereas in men this association was only evident during the course of treatment [3].

The literature also highlights a differential pattern of adverse effects according to vaccine type and age, particularly in young women. A multicenter study conducted in Japan compared the Pfizer, Moderna, and AstraZeneca vaccines and found that women under 30 years of age more frequently exhibited delayed cutaneous reactions, especially following the Moderna vaccine, which were observed around the eighth day after the first dose. These reactions included localized erythema, pruritus, and inflammation symptoms that were more persistent compared to males within the same age group [4].

In the case of pregnant women with autoimmune rheumatologic inflammatory diseases, a study involving 1,413 participants revealed that, although there were no significant differences in the total number of adverse effects between women with and without autoimmune diseases, those with greater functional disability (assessed by the HAQ-DI index) exhibited a higher number of systemic reactions following vaccination ($\beta = 0.56$; 95% CI: 0.04–1.10) [5]. This suggests that not only sex but also the underlying clinical condition influences the experience of adverse reactions.

The relevance of this approach is also evident in severe oncological and autoimmune contexts. For instance, in a patient with systemic lupus erythematosus and antiphospholipid syndrome, CAR-T cell therapy targeting B cells enabled sustained eradication of three subtypes of antiphospholipid antibodies, suggesting the potential use of cellular immunotherapy as a curative strategy in procoagulant autoimmune diseases [6]. This case not only highlights the therapeutic potential of advanced immunotherapies in women but also underscores the risks that must be carefully monitored in terms of toxicity, immune dysfunction, or unpredictable side effects.

Additionally, during pregnancy, the immune response dynamically adapts to tolerate the fetus, thereby modifying the response to therapeutic agents. Studies involving pregnant women with immune thrombocytopenia (ITP) indicate that risks of hemorrhage and toxicity must be carefully managed, as the immunological progression differs compared to non-pregnant women with the same condition [7]. Similarly, in women with neuromyelitis optica spectrum disorder (NMOSD), it has been shown that maintaining immunosuppressive treatment during pregnancy significantly reduces relapses, although it is associated with an increased risk of adverse birth outcomes (OR = 3.73; 95% CI: 1.40–9.91) [8].

In this context, bibliometrics emerges as a powerful tool to systematically analyze scientific trends, knowledge gaps, and focal points surrounding this issue. Through co-occurrence term analysis, collaboration networks, and impact metric evaluation, it is possible to accurately map the historical and thematic development of research on adverse effects in women related to immunological and pharmacological therapies.

This study proposes a detailed bibliometric analysis encompassing reported adverse effects from clinical studies and case reports, as well as controversies surrounding the safety of vaccines, biologics, and immunomodulatory drugs in female populations. Additionally, it highlights the role of genetic factors such as HLA haplotypes in susceptibility to adverse events, the influence of comorbidities, the importance of the obstetric context, and the necessity of incorporating a gender-based approach in the design of therapeutic strategies [9] [2] [1].

Ultimately, highlighting the interrelationship between women, immunology, and pharmacological adverse effects addresses not only a scientific need but also an ethical and social imperative. Recognizing the biological and clinical particularities of the female sex in immune and therapeutic responses promotes the development of personalized, inclusive, and evidence-based medicine.

Immunological Adverse Effects in Women: A Clinical and Therapeutic Perspective

Scientific evidence has established that women exhibit a higher incidence of immunological adverse effects in response to various pharmacological and immunotherapeutic treatments. This differential susceptibility is determined by multiple factors, including a more active immune response, elevated levels of circulating antibodies, and increased expression of immunity-related genes on the X chromosome [1]. While such

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characteristics confer more effective protection against infections, they also predispose women to heightened immunological reactivity to drugs, vaccines, and targeted therapies, resulting in adverse events of varying severity. A paradigmatic example is oncological immunotherapies. In women treated with PD-1 immune checkpoint inhibitors (anti-PD-1), a high prevalence of immune-mediated adverse events has been observed, particularly thyroid dysfunction associated with the presence of thyroid autoantibodies. In a study involving 143 melanoma patients treated with anti-PD-1, women with baseline seropositivity for thyroid autoantibodies developed thyroid dysfunction in 100% of cases, whereas in men this association was only evident during treatment (not at baseline), indicating a fundamental immunological difference that affects the toxicity profile [3]. This finding demonstrates not only the relevance of autoantibodies as predictive biomarkers of adverse events but also the necessity of conducting sex-specific studies prior to initiating immunotherapy.

Furthermore, rare but clinically relevant immunological adverse effects affecting exclusively women have been reported. A significant example involves a woman treated with Avelumab, a PD-L1 inhibitor, who developed treatment-induced cutaneous sarcoidosis. The granulomatous reaction was initially mistaken for metastatic progression, but histopathological analysis revealed chronic dermal infiltrates with multinucleated giant cells and asteroid bodies, characteristic of sarcoidosis [10]. This type of immunological reaction illustrates how adverse effects in women can manifest with atypical clinical presentations, complicating diagnosis and therapeutic continuity.

Conversely, in the context of CAR-T therapy, traditionally associated with the treatment of hematological malignancies, a profound immunomodulatory effect has been observed in women with severe autoimmune diseases. In a documented case, a woman with systemic lupus erythematosus and refractory antiphospholipid syndrome, after receiving anti-CD19 CAR-T therapy as part of treatment for an aggressive lymphoma, experienced sustained eradication of the three antiphospholipid antibody subtypes (anticardiolipin, anti-beta2-glycoprotein I, and lupus anticoagulant) [6]. This outcome not only suggests a potential therapeutic effect on autoimmune mechanisms but also raises important questions regarding unforeseen immunological risks in women with systemic diseases and the need for prolonged monitoring.

In immunoregulated gynecological diseases such as endometriosis, an abnormal immune response has also been described as a pathogenic factor. Recent studies have developed targeted nanoparticles that modulate the female immune microenvironment. In particular, a formulation based on albumin and mifepristone (BSA@Mif NPs) has proven effective by inducing immunogenic cell death and repolarizing M2-type macrophages toward an M1 phenotype, thereby reducing the proliferation of ectopic endometrial cells in murine models [11]. These results underscore the importance of therapeutic strategies that prioritize immunomodulation as a central axis, especially in diseases that predominantly affect women.

Additionally, cutaneous autoimmune diseases such as pemphigus vulgaris have demonstrated a more complex clinical course in women. A clinical case of a 65-year-old woman with severe and recurrent pemphigus showed the effectiveness of intravenous immunoglobulin (IVIg) as a rescue therapy, although adverse effects such as headache and fatigue persisted even after switching to a higher-purity IVIg formulation [12]. This persistence of side effects highlights the need to evaluate not only the efficacy but also the long-term tolerability of immunological therapies in women.

It is important to note that immunological adverse effects are not limited to pathological contexts. Even treatments considered innocuous, such as vaccines, have shown a higher frequency of adverse reactions in women. In a comparative study of COVID-19 vaccines (Pfizer, Moderna, and AstraZeneca), it was identified that women experienced more local and systemic adverse events, with delayed cutaneous reactions (such as erythema and pruritic inflammation) being significantly more frequent in women under 30 years of age, particularly with the Moderna vaccine [4].

In summary, immunological adverse effects in women constitute a critical clinical dimension that requires personalized approaches with a gender perspective. The evidence presented demonstrates that both modern immunotherapies and preventive strategies (such as vaccines) elicit distinct immune responses in women, often more intense and with greater clinical implications. Recognizing these patterns is essential not only to optimize treatments but also to ensure safety, efficacy, and equity in women's healthcare.

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Vaccines, Autoimmunity, and Gender: Risks in Female Populations

Vaccination represents one of the most effective strategies in public health but has also revealed substantial differences in immune response and tolerance between men and women. Numerous studies have shown that women, due to their heightened immune reactivity, tend to develop post-vaccination adverse effects both local and systemic more frequently than their male counterparts [4]. This heightened reactivity is further amplified in women with preexisting autoimmune diseases, during pregnancy, or in periods of increased immunological sensitivity, such as lactation.

One of the most representative studies on this issue was conducted in Japan with a large cohort receiving Pfizer, Moderna, and AstraZeneca vaccines. The results showed that women, particularly those under 30 years of age, more frequently exhibited delayed cutaneous reactions, especially with the Moderna vaccine. These reactions, characterized by pruritic erythema at the injection site, appeared around the eighth day and resolved within approximately 10 days [4]. At the systemic level, fever was more common in women following the second dose of mRNA vaccines (Moderna and Pfizer), in contrast to the AstraZeneca vaccine, which exhibited more pronounced effects after the first dose [4].

The interaction between autoimmunity and vaccination is particularly relevant in women with autoimmune inflammatory rheumatic diseases (AIIRD). In a cohort study of 1,413 pregnant women vaccinated against COVID-19, 79 had AIIRD. Although no differences were observed in the overall frequency of adverse reactions between women with and without AIIRD ($\beta = -0.01$; 95% CI: −0.17 to 0.17), it was evident that women with higher disability indices (high HAQ-DI) developed more systemic reactions ($\beta = 0.56$; 95% CI: 0.04 to 1.10) [5]. This suggests that not only autoimmunity per se, but also the degree of disease activity or functional impact, may predispose to more intense vaccine responses.

Conversely, a global survey conducted within the framework of the COVAD study (COVID-19 Vaccination in Autoimmune Diseases), involving 9,201 participants, demonstrated that pregnant women with autoimmune diseases reported significantly more adverse effects following vaccination than non-pregnant women with the same conditions (overall adverse events: 45% vs. 26%, $p = 0.01$; major events: 17.5% vs. 4.6%, $p < 0.01$). These patients also exhibited a post-vaccination relapse rate of 17.5%, which was primarily managed with corticosteroids, and in some cases required adjustments in immunosuppressive therapy [2]. This finding demonstrates that pregnancy not only modifies immunity but may also amplify vaccine-related adverse effects in the presence of underlying autoimmune disease.

In parallel, another study based on the MotherToBaby cohort, involving pregnant women with AIIRD in the United States and Canada, reported no differences in the total number of adverse effects between women with and without AIIRD. However, similar to the previous study, those with greater functional impairment experienced more mild systemic effects following vaccination [5]. This finding supports the hypothesis that active or uncontrolled autoimmunity influences vaccine reactivity, particularly in contexts of modified immunotolerance such as pregnancy.

Even in women without autoimmunity but exposed to vaccines in experimental contexts, a higher incidence of adverse events has been observed. For example, in an active surveillance study in Ghana on the Pfizer and Moderna vaccines, women exhibited a higher overall incidence of adverse events (20.4% for Moderna vs. 14.0% for Pfizer), with frequent symptoms including headache, fever, fatigue, and injection site pain [13]. Although no severe events were reported, the study highlighted that factors such as the vaccination center and the presence of chronic medical conditions influenced the risk of adverse events, with women being more susceptible in both cases [13]

Beyond COVID-19 vaccines, studies on maternal immunization against respiratory syncytial virus (RSV) have also yielded relevant results. In a subanalysis of the MATISSE trial conducted in Japan, the RSVpreF vaccine was well tolerated by pregnant women, with no significant differences in adverse effects between the vaccinated and placebo groups [14]. However, subgroup analysis detected slight variations in local events and rates of preterm birth, highlighting the need for more specific studies with a gender perspective.

Finally, it must be considered that risk perception also influences vaccine acceptance among women. In a survey conducted in Sub-Saharan Africa, pregnant women exhibited lower risk perception toward COVID-19 (mean: 3.74 vs. 5.78, $p < 0.001$) and less willingness to be vaccinated (OR = 0.12; 95% CI: 0.06–0.27), with perceived

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vaccine safety being one of the main reasons for refusal [15]. These perceptions, shaped by sociocultural and healthcare contexts, interact with actual immunological risks and represent additional barriers to achieving equitable and effective vaccine coverage among women.

Table 1. Comparison of Post-Vaccination Adverse Effects in Women According to Study

Study (Reference)	Population	Vaccines Evaluated	Main Adverse Effects in Women	Key Observations
[4]Japón	Women <30 years	Pfizer, Moderna, AstraZeneca	Fever, delayed cutaneous reactions, pain	Moderna associated with more events
[5] USA-Canadá	Pregnant Women with AIIRD	COVID-19 (general)	Mild systemic reactions in high HAQ-DI	Moderate risk
[2] COVAD global	Pregnant Women with AID	COVID-19	17.5% with post-vaccination relapses	Need for immunomodulation
[13] Ghana	Women Vaccinated with mRNA Vaccines	Pfizer, Moderna	Headache, fever, local pain	Moderna with higher incidence
[14] Japón (MATISSE)	Pregnant	RSVpreF	No significant differences	High efficacy, good tolerability

Autoimmune Diseases and Therapeutic Complications in Women

Autoimmune diseases disproportionately affect women, accounting for more than 75% of cases globally, and frequently manifest during reproductive ages. This prevalence has driven the study of the interaction between immunomodulatory treatments and adverse responses in this population. However, despite the high disease burden, therapeutic regimens have not always been designed or evaluated with a gender perspective, leading to significant clinical risks.

One of the most complex aspects in women with autoimmune diseases is managing therapy during pregnancy. For example, in women with immune thrombocytopenia (ITP), treatment must be carefully adjusted to avoid both maternal bleeding and fetal adverse effects. Although the immunological progression of ITP during pregnancy shares characteristics with the non-pregnant form, treatment-related toxicity risks demand differentiated strategies [7]. The use of corticosteroids and intravenous immunoglobulin (IVIg) is common, but their efficacy and safety require close monitoring during pregnancy.

Neuromyelitis optica spectrum disorder (NMOSD), a severe autoimmune disease of the central nervous system, has been the subject of multiple investigations regarding therapeutic complications in women. In a meta-analysis of cases positive for AQP4 antibodies, it was demonstrated that maintaining immunosuppressive treatment during pregnancy significantly reduces relapses, with a risk ratio (RR) of 0.35–0.62 ($p < 0.0001$). However, this clinical benefit is accompanied by an increased risk of adverse effects in newborns, which are 3.73 times more frequent than in untreated cases (95% CI: 1.40–9.91) [8]. These data underscore the need to personalize dosing and closely monitor the maternal-fetal immune response.

Unexpected complications have also been documented with advanced biological therapies. A particularly relevant case involved a patient with systemic lupus erythematosus and antiphospholipid syndrome who, after receiving CAR-T cell therapy against aggressive B-cell lymphoma, experienced complete disappearance of the three antiphospholipid antibody subtypes [6]. This outcome suggests a promising therapeutic potential for refractory autoimmune diseases but also raises questions about the immunological impact of such therapies on already hyperactive systems, as seen in many women with systemic autoimmune pathologies.

Conversely, in inflammatory dermatological diseases such as pemphigus vulgaris, persistent adverse effects have been reported even with high-purity treatments. In a 65-year-old patient, the use of intravenous immunoglobulin (IVIg) stabilized the disease but did not significantly reduce the occurrence of side effects such as fatigue and headache, even after switching to a formulation with an improved tolerability profile [12]. These results indicate that, in women with severe autoimmune diseases, the baseline immunological profile may influence the ongoing occurrence of adverse events beyond pharmacological adjustments.

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MDA5 antibody-associated dermatomyositis amyloidosis is another autoimmune disease in which women exhibit a more severe clinical course and resistance to conventional treatments. In a clinical case, a patient treated with Upadacitinib (a JAK inhibitor) demonstrated complete remission within six weeks without adverse events or relapses, along with sustained reduction of antibody titers [16]. This suggests that selective JAK inhibitors could represent a safe and effective therapeutic option for women with refractory cutaneous autoimmune diseases.

From a deeper immunological perspective, the role of the innate immune system and the tumor microenvironment has been explored in women with endometriosis, a disease that shares mechanisms with autoimmunity. In a recent study, nanoparticles targeting M2-type macrophages were developed, successfully reversing immunological polarization and reducing the proliferation of ectopic endometrial cells [11]. These sex-specific immunomodulatory strategies represent a promising frontier in the treatment of female immunological diseases.
In summary, women with autoimmune diseases face unique therapeutic challenges due to both their immunological predisposition and differential side effects to conventional and advanced immunotherapies. Managing these patients requires a personalized approach that integrates immunological biomarkers, reproductive history, comorbidities, and strict monitoring of adverse effects, particularly during pregnancy or menopausal transition.

Table 2. Immunological Therapies and Reported Complications in Women with Autoimmune Diseases

Disease	Treatment	Reported Immunological Adverse Effects	References
ITP in Pregnancy	Corticoides, IVIg	Risk of Fetal Toxicity and Maternal Bleeding	[7]
NMOSD	Immunosuppressants During Pregnancy	Reduction of Relapses, but Increased Neonatal Risk (OR 3.73)	[8]
LES + SAF	CAR-T anti-CD19	Eradication of Antiphospholipid Autoantibodies, Unknown Risk	[6]
Pemphigus Vulgaris	IVIg	Fatigue, Persistent Headache, Poor Long-Term Tolerability	[17]
ADM anti-MDA5	Upadacitinib (JAKi)	Complete Remission Without Relapses or Adverse Effects	[16]
Endometriosis	Nanoparticles Targeting M2 Macrophages	Reversal of Local Immunosuppression Without Systemic Toxicity	[11]

Immunological Risks During Pregnancy and Lactation
Pregnancy represents a complex immunological state in which the maternal organism must develop specific immune tolerance toward the fetus without compromising its defense against pathogens. This condition renders pregnant women particularly susceptible to immunological alterations induced by pharmacological, vaccine-related, or biological therapies. During lactation, challenges persist associated with the possible transfer of immunoactive compounds or pharmacological residues through breast milk, extending the risk sphere beyond the mother-fetus dyad to the nursing neonate.

In the context of COVID-19 vaccination, various studies have confirmed that pregnant women with autoimmune diseases exhibit a more reactive immunological profile in response to immunization. The international COVAD study demonstrated that pregnant women with autoimmune pathologies had a significantly higher incidence of both general and major adverse effects compared to non-pregnant women with the same conditions (general adverse effects: 45% vs. 26%; major events: 17.5% vs. 4.6%, $p < 0.01$) [2]. Additionally, a considerable percentage of post-vaccination relapses (17.5%) was identified, which in some cases required modification of immunosuppressive treatment [18].

Although no significant differences in adverse effect patterns were observed between lactating women with autoimmune diseases and healthy lactating women, the post-vaccination relapse rate reached 20% in the former group [2]. Most of these relapses were managed with corticosteroids, although a significant proportion required initiation or modification of immunosuppressive treatments, reflecting the need for specific immunological monitoring protocols during the lactation period.

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Por otro lado, estudios que analizan la seguridad de vacunas en contextos materno-fetales han reportado resultados tranquilizadores, como en el caso de la vacuna RSVpreF contra el virus sincitial respiratorio, administrada durante el tercer trimestre del embarazo. Este estudio no detectó diferencias significativas en la aparición de eventos adversos entre los grupos vacunados y placebo, y tampoco en las tasas de parto prematuro o de efectos adversos neonatales, lo que sugiere una buena tolerabilidad de esta intervención en mujeres gestantes sanas [14].

In the context of non-communicable autoimmune diseases, the need for specific therapeutic adjustments during pregnancy has been identified to ensure both maternal immunological stability and fetal safety. For example, in women with immune thrombocytopenia (ITP), it has been demonstrated that therapeutic management must be carefully differentiated from gestational thrombocytopenia to avoid unnecessary treatments or bleeding risks. Administration of corticosteroids or intravenous immunoglobulin may be effective, but their use requires strict monitoring to prevent fetal toxicities and undesired immunosuppressive effects [7].

In the context of HIV treatment in pregnant women, a study conducted on African seroconverted women within the anti-VRC01 broadly neutralizing antibody trial evaluated the possibility of temporarily interrupting antiretroviral therapy. Among the women who discontinued treatment under controlled conditions, 18% maintained sustained viral control for at least 32 weeks without the need to reintroduce therapy, and without severe adverse events or vertical transmission of the virus [19]. Although the results were promising, the detection of residual tenofovir levels in some participants suggests the need for cautious interpretation of these findings and further studies to confirm the feasibility of this strategy.

In the case of preventable congenital infections such as cytomegalovirus (CMV), the use of hyperimmune immunoglobulin (HIG) during the first trimester of pregnancy did not show a significant reduction in the rate of vertical transmission. In this study, the overall transmission rate was 29.9%, and no significant differences were observed between women who initiated treatment in the first or second trimester of pregnancy, positioning maternal viremia as a more reliable predictor of fetal risk than the timing of immunological intervention [20].

Furthermore, during the postnatal period, breastfeeding is often interrupted in women with autoimmune diseases due to concerns about the adverse effects of immunosuppressants on the neonate. In a study conducted with patients with systemic lupus erythematosus, it was found that only 36.7% of mothers initiated breastfeeding, compared to 86.7% of mothers without autoimmune diseases ($p < 0.001$) [21]. The primary reported reason was fear that the medications consumed could harm the baby, despite the fact that multiple immunosuppressants commonly used in this population are considered compatible with breastfeeding.

Taken together, the evidence indicates that pregnant and lactating women with immunological diseases or receiving immunoactive treatments require differentiated care protocols. These protocols must consider not only the altered pharmacokinetics during these stages but also maternal immune reactivity, the risk of vertical transmission, neonatal safety, and the impact on maternal mental health, often conditioned by therapeutic uncertainty. Therefore, incorporating a gender perspective in immunological safety assessment is not only desirable but essential to achieve truly equitable and safe medicine.

Application of PRISMA and Women, Immunology, and Therapy

The use of the PRISMA methodology (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) has been established as a fundamental tool in conducting systematic reviews aimed at synthesizing and critically analyzing the available scientific evidence. In the specific context of studies on women, immunology, and therapy, this methodology has not only ensured transparency and methodological rigor but has also highlighted particular issues such as the underrepresentation of women in biomedical research and the insufficiency of sex-disaggregated data in the analysis of adverse drug effects.

Several systematic reviews included in this bibliometric analysis have adopted the PRISMA approach to structure their searches, study selection, and synthesis of results. For example, in assessing the impact of co-infection by human papillomavirus (HPV) and HIV in immunocompromised women, the PRISMA 2020 criteria were applied to review 84 articles retrieved from databases such as Web of Science, PubMed, and Scopus. This enabled a robust synthesis of the prevalence of oncogenic HPV genotypes and cervical cancer biomarkers in the female population [22]. This approach facilitated the identification of a high burden of persistent HPV infection in women with HIV, with significant clinical implications for immunological surveillance and therapeutic strategies.

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Similarly, in a systematic review focused on the safety of COVID-19 vaccines in pregnant women, PRISMA was used to select studies conducted between 2019 and 2021, encompassing 46,264 pregnancies and reporting comparable adverse effect profiles between pregnant and non-pregnant women. This review demonstrated that the use of mRNA vaccines did not increase the risks of miscarriage or congenital malformations, thereby contributing to clinical decision-making in a population historically excluded from clinical trials [23].

Similarly, the PRISMA protocol was fundamental in studies on stiff-person syndrome (SPS), an autoimmune neurological condition that predominantly affects women. The methodology standardized the inclusion of 14 studies on the use of rituximab as an immunomodulatory treatment, with clinical improvements observed in the majority of patients despite heterogeneity in therapeutic regimens and a lack of consistent correlation with anti-GAD antibody titers [24]. This case demonstrates the utility of PRISMA in synthesizing fragmented evidence in rare conditions that predominantly affect women and where clinical research is limited.

At the structural level, PRISMA has also been applied to examine gender representation patterns in high-impact clinical research. A study on clinical trials of CAR-T therapies in hematology-oncology revealed, through a PRISMA selection flow, that only 29.5% of the authors were women, and just 7 out of 15 studies had female lead authorship, highlighting a persistent gender gap in the field of advanced cellular therapy [25]. These findings not only reflect disparities in research leadership but also the possible omission of gender perspectives in the design and analysis of clinical studies on immunological therapies.

It is noteworthy that PRISMA functions not only as a reporting guideline but also as a structural framework to examine the methodological quality of evidence on adverse drug effects in women. The combination of this tool with bibliometric analyses enables mapping knowledge gaps and guiding future research agendas toward more equitable medicine. In particular, the use of PRISMA allows filtering studies that include sex-disaggregated data, identifying vulnerable populations such as pregnant women, immunocompromised patients, or those with autoimmune disorders, and systematically evaluating the efficacy and safety of new therapies, including biologic agents like dupilumab in atopic dermatitis [26] or rituximab in neurological disorders [24].

In summary, the application of PRISMA in the analysis of scientific literature related to women, immunology, and therapies has enhanced the visibility of gender biases, facilitated the systematization of dispersed clinical data, and highlighted the need to include sex and gender variables in therapeutic research. These contributions are fundamental to ensuring that women are considered not only as beneficiaries but as central subjects in the generation and application of biomedical knowledge.

Hypothesis Statement

This study establishes two main research questions and hypotheses:
The first question posed is: Does the analysis of bibliometric measures allow for the assessment of immunological trends related to adverse drug effects in women and pharmacological therapies?

H1**:** The analysis of bibliometric measures enables the identification and characterization of the main immunological trends associated with adverse effects of pharmacological therapies in women, revealing research patterns, thematic gaps, and emerging areas within the field.
Hypothesis 1 aims to analyze the results of key bibliometric indicators and understand the trend of scientific production related to our study topic.
The second question concerns: Does the analysis of author-defined term networks allow for determining the challenges of adverse drug effects related to women in immunology?

H2**:** The analysis of co-occurrence networks of author-defined terms permits the identification and categorization of the main challenges associated with adverse drug effects in women within the field of immunology.
The network analysis of co-occurring conceptual terms defined by the authors allows for determining the most relevant clusters of trends and challenges related to the study topic.

METHODS

Selection of documents

For the selection of documents, we applied the best practices defined by the PRISMA methodology. In Figure 1, we present the workflow designed for the document selection process.

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Search equations were developed for document retrieval (see Table 1) corresponding to each of the databases. As clarifying information, no records related to the study topic were found in the Scopus database.

Figure 1. WorkFlow PRISMA

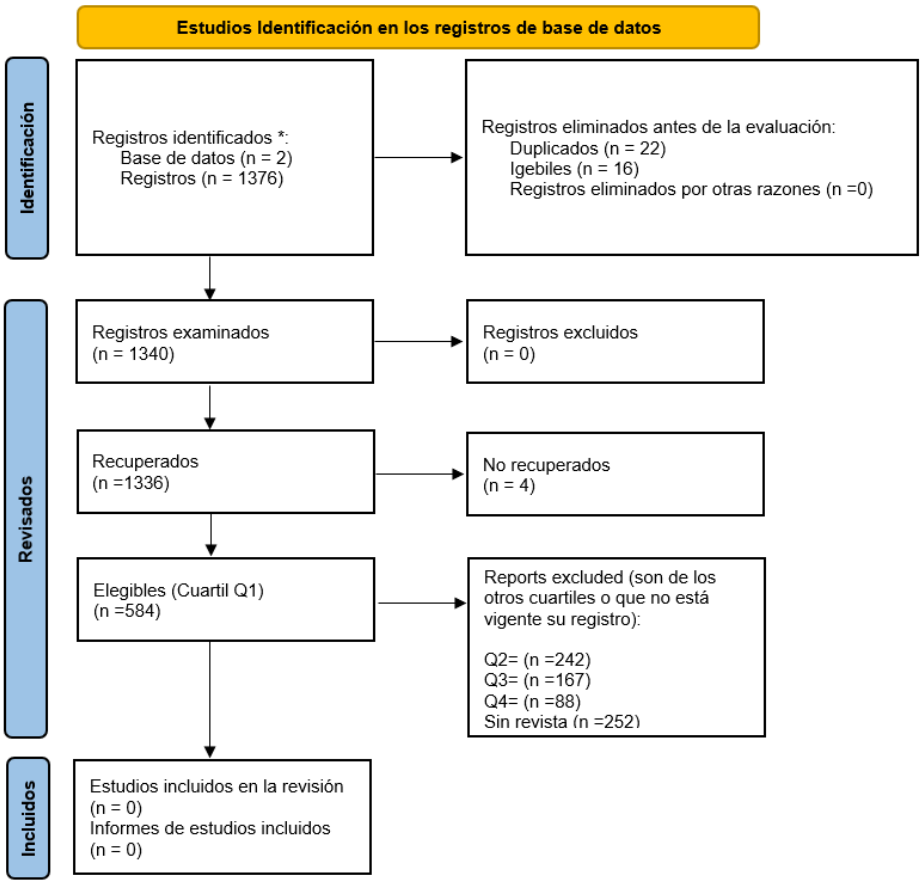

Table 1. Search Equiations

Data base	Search Equations	registros recuperados
Web Of Sciencie	immunology OR "immune system" OR "immunologic response" (All Fields) And women OR woman (All Fields) And "adverse effects" OR "side effects" OR toxicity OR "drug reactions" OR "pharmacovigilance" (All Fields) And therapy OR treatment OR medication OR drugs (All Fields)	386
Scopus	TITLE-ABS-KEY ((immunology OR "immune system" OR "immunologic response") and (women OR woman) and ("adverse effects" OR "side effects" OR toxicity OR "drug reactions" OR "pharmacovigilance") and (therapy OR treatment OR medication OR drugs)) AND (LIMIT-TO (DOCTYPE , "ar"))	990
	Total de Registros recuperados	1376

Bibliometric analysis Workflow

For the present bibliometric analysis, the following workflow was developed:

1. Article records related to the study topic were downloaded in BibTeX format from the corresponding databases.

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2. Using Python programming, all BibTeX files were merged, removing duplicate records, resulting in a total of 1,340 articles.
3. Through Python scripting, articles from journals classified in the Q1 quartile according to records defined by each database were selected, yielding a total of 548 articles.
4. Bibliometric measures were extracted using the Bibliometrix tool, version 5.
5. Using VOSviewer version 1.6.20, a co-occurrence conceptual term network was designed, and the four main clusters were extracted

RESULTS

Analysis of Bibliometric Measures

The bibliometric analysis of scientific production related to women, immunology, and adverse effects of pharmacological therapies enabled the identification of a consolidated and continuously evolving knowledge base (see Figure 2). The study period spanned five decades, from 1975 to 2025, considering only journals associated with the Q1 quartile of the Scopus and Web of Science databases, respectively, totaling 548 articles distributed across 245 distinct sources. The average annual growth rate of production was 6.28% (see Figure 3A), reflecting sustained development in research on this thematic intersection, particularly during the last two decades.

The average age of the documents is 10.1 years, suggesting a body of literature with significant historical background yet still relevant. This is complemented by an average of 58.79 citations per document (see Figure 3B), indicating a high level of scientific impact and interest in the topic under study. Collectively, the analyzed works reference a total of 7,790 sources, reflecting a robust citation network that spans multiple disciplines, particularly in the fields of medicine, immunology, pharmacology, and gender studies.

Regarding thematic content, 7,080 Keywords Plus (ID) and 991 author keywords (DE) were identified, indicating a rich conceptual diversity and high thematic specificity in the scientific production. This abundance of terms reflects the evolution of methodological and conceptual approaches used to address the issue of adverse drug effects in women from an immunological perspective (see Figure 3C).

Authorship analysis revealed the participation of 5,109 researchers, of whom only 11 documents were single-authored, while the average number of co-authors per publication was 10.1. This indicates a high degree of scientific collaboration.

Collectively, these results reveal a consolidated scientific production with a positive trend, which has established a solid knowledge base on the immunological adverse effects of pharmacological treatments in women. The thematic breadth, impact measured by citation counts, and high author collaboration constitute essential pillars for understanding scientific evolution and the knowledge gaps yet to be addressed in future interdisciplinary research.

Figure 2. Biliometric measures

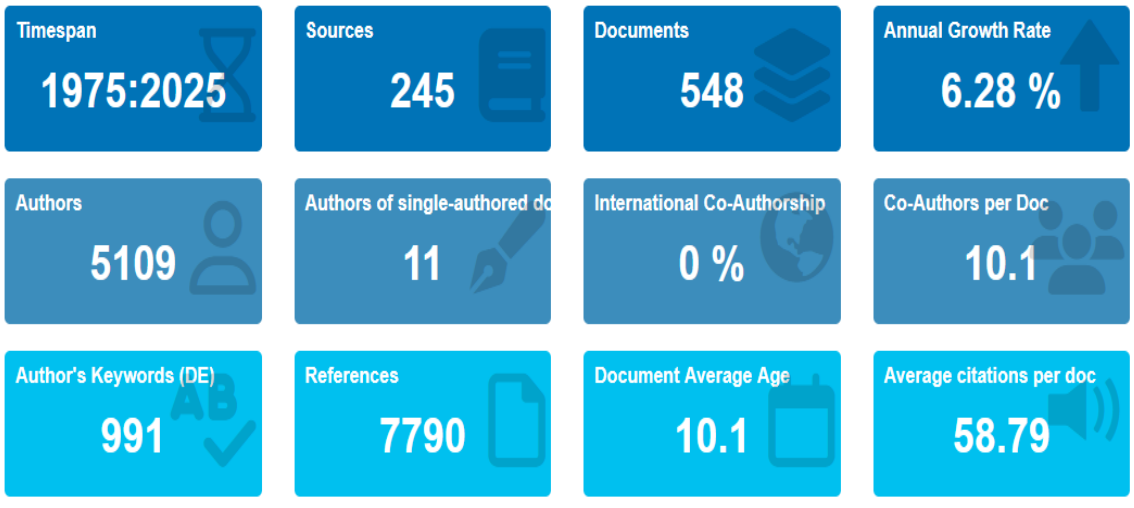

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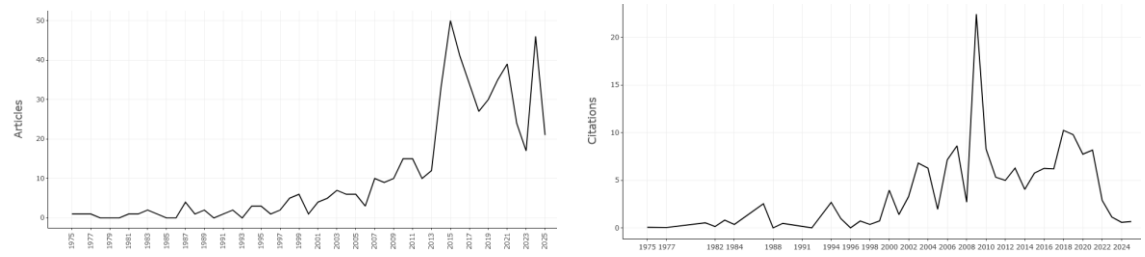
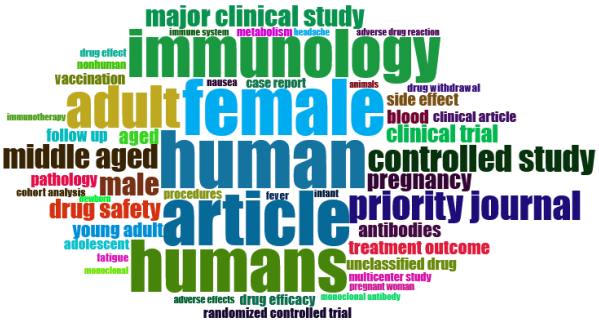
Figure 3. Evolution of scientific production

A B



C

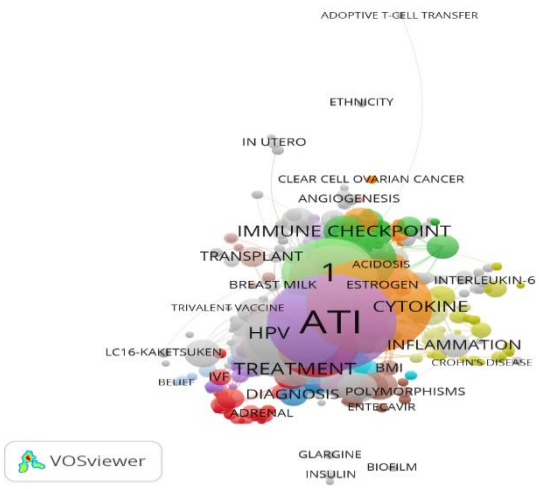


Note: A) Annual Scientific Production. B) Average Citations Per Year and C) WordCloud

Analysis of Conceptual Term Co-Occurrence Network

From the processing of 548 articles, a total of 991 conceptual terms defined by 5,109 authors were identified. A conceptual term network was designed (see Figure 4). Additionally, using the VOSviewer tool, four main clusters were selected that concentrate the highest degree of association among terms. The first cluster was defined as: Immunoregulation and Reproductive Therapies in Women with Immunological Dysfunction. The second cluster relates to: Oncological Immunotherapy and Immune-Mediated Adverse Events with Metabolic Impact. The third cluster was associated with: Vaccines, HIV, and Maternal-Infant Immunological Health in Vulnerable Contexts. Finally, the fourth cluster was defined as: Biological Therapies and Immunometabolic and Perinatal Impact in Women with Chronic Diseases. A literature review of articles related to each of these clusters is presented below.

Figure 4. co-occurence Network



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Cluster 1: Immunoregulation and Reproductive Therapies in Women with Immunological Dysfunction.
This cluster groups research focused on the intersection of reproductive immunology, pharmacological therapies, and female infertility, highlighting the role of immunoregulation in processes such as embryo implantation, fertilization, and successful pregnancy (see Figure 5). The studies analyzed reveal that women with immunological dysfunctions such as antiphospholipid syndrome, chronic endometritis, or imbalances in uterine NK cells and regulatory T lymphocytes exhibit higher rates of recurrent reproductive failure and embryo implantation failure, even following in vitro fertilization (IVF) treatments (FIV) [27,28,21].

The use of personalized immunotherapies is emphasized, including intravenous immunoglobulin (IVIG), glucocorticoids, intralipids, low molecular weight heparin, and immunosuppressive agents to modulate the maternal immune response and improve embryo tolerance [29–31]. Additionally, some studies address the efficacy of therapeutic combinations including aspirin, prednisone, cyclosporine, and plasmapheresis, particularly in patients with complex immunological diagnoses [32,8,6].

Another relevant aspect in the abstracts is the involvement of immunological biomarkers such as the expression of BAFF, BLyS, or Th1/Th2 cytokine profiles in predicting reproductive success, as well as the need to perform advanced immunological tests like uterine NK cell detection, autoantibody panels, and evaluation of the endometrial microenvironment [33,2]. These studies emphasize the importance of individualized immunological evaluation in women with a history of unexplained infertility, recurrent miscarriages, or repeated failures in assisted reproductive technologies [8,34].

The content of this cluster also reveals a growing concern regarding the adverse effects of immunomodulatory therapies on renal function, hormonal balance, and maternal-fetal health, highlighting the need for safer, evidence-based therapeutic strategies [35].

Collectively, this cluster highlights a critical research area for female reproductive health, integrating clinical immunology, endocrinology, and reproductive medicine, and proposing an interdisciplinary and personalized approach to the treatment of infertility associated with immunological dysfunction [6].

Cluster 2: Oncological Immunotherapy and Immune-Mediated Adverse Events with Metabolic Impact.
This cluster groups research focused on modern immunotherapeutics, particularly immune checkpoint inhibitors, used in oncology. There is growing concern regarding their adverse effects, both immunological and metabolic, including the induction of autoimmune diabetes, pancreatic disorders, and severe systemic toxicities. The inclusion of terms related to mathematical modeling also suggests that some of these studies explore strategies to predict or model these effects (see Figure 5).

This cluster focuses on immune-mediated side effects associated with the use of immunotherapy in oncology patients, with particular emphasis on metabolic disturbances that compromise the physiological balance of the organism. Immunotherapy, especially through immune checkpoint inhibitors (ICI), has revolutionized cancer treatment by enhancing the immune system's response against tumor cells. However, this immune activation is not without adverse consequences, notably autoimmune events affecting organs and systems, including energy metabolism, endocrine, and glycemic regulation [36,37].

A recurring focus in studies within this cluster is the emergence of endocrine dysfunctions induced by immunotherapy, such as hypophysitis, autoimmune thyroiditis, and sudden-onset diabetes mellitus. These manifestations, which may occur following administration of drugs like nivolumab, pembrolizumab, or ipilimumab, reflect profound disruption of metabolic homeostasis in patients, necessitating thorough clinical monitoring and interdisciplinary management strategies [38,39,17].

Additionally, cases of diabetic ketoacidosis, severe dyslipidemias, and complex metabolic syndromes have been reported, which not only complicate oncological treatment but may also compromise quality of life and long-term survival. These adverse effects reflect dysregulated immune activation that does not distinguish between tumor cells and healthy tissues, particularly affecting key organs involved in metabolic regulation such as the pancreas, liver, and adipose tissue [40,41].

The included studies also emphasize the importance of identifying predictive biomarkers to anticipate the onset of these adverse events. The roles of proinflammatory cytokines, immunophenotypic profiles, and autoimmune

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history are being investigated as risk factors that could guide safer and more personalized therapeutic decisions. Additionally, the potential integration of artificial intelligence and clinical prediction models is being explored for early monitoring of metabolic effects in patients undergoing immunotherapy [42,43].

An emerging aspect within this cluster is the need to rethink monitoring and treatment protocols for these patients from a comprehensive approach that considers both the antitumor benefits of immunotherapy and its potential disruptive effects on metabolism. Collaboration among oncologists, endocrinologists, immunologists, and metabolism specialists becomes crucial to establish more effective and less invasive care pathways that include early interventions, nutritional management, and psychosocial support [44,45].

In summary, Cluster 2 highlights a critical dimension of oncological immunotherapy: its metabolic impact through immune-mediated adverse events. Understanding this complex interplay between immunity and metabolism not only allows for improved treatment safety but also optimizes clinical care for cancer patients within a framework of personalized and multidisciplinary medicine.

Cluster 3: Vaccines, HIV, and Maternal-Infant Immunological Health in Vulnerable Contexts.
This cluster groups studies on the immune response to infectious agents and their treatment in women, with an emphasis on vulnerable populations (such as mothers and children in endemic regions). The literature focuses on the immunological impact of vaccines, pharmacovigilance in women, and adverse effects derived from antiretroviral drugs. The intersection of immunology, gender, and global public health is highlighted, including epidemiological components and health program evaluations (see Figure 5).

This cluster focuses on studies addressing the intersection of vaccination, HIV infection, and maternal-infant immunological health, with a specific emphasis on populations living under conditions of high social, economic, and healthcare vulnerability. This thematic line underscores the importance of implementing effective, sustainable, and culturally adapted immunization strategies, particularly in regions where structural gaps hinder access to essential medical services [46,47].

One of the main focuses of this cluster is the evaluation of the effects of HIV infection in pregnant women and its immunological implications for both the mother and the newborn. The analyzed studies reveal that virus-induced immunosuppression compromises the efficacy of vaccines administered during pregnancy, reducing placental antibody transfer and increasing the risk of vaccine-preventable neonatal infections [30,48]. This situation is exacerbated in contexts where diagnostic and therapeutic resources are limited, disproportionately affecting rural, indigenous, or displaced communities.

Another relevant finding is the analysis of vaccination schedules in HIV-exposed children who, despite being seronegative, exhibit immunological alterations affecting their response to vaccines such as BCG, pentavalent, hepatitis B, and pneumococcal vaccines. The literature suggests the need to adjust vaccination strategies in this population, including additional boosters, changes in the schedule, or the use of conjugate vaccines with enhanced immunogenicity [49–51].

Furthermore, studies within this cluster highlight the role of mothers as key agents in ensuring continuity of the childhood immunization schedule. Factors such as educational level, HIV-related stigma, misinformation, and geographical barriers directly influence vaccine coverage. Some research proposes community support programs, intercultural communication, and maternal empowerment as effective mechanisms to increase adherence to vaccination schedules and improve the immunological health of infants [52–54].

Global and regional initiatives aimed at strengthening maternal-infant immunological health have also been identified, including public-private partnerships, reinforcement of primary healthcare networks, and integration of mobile technologies for monitoring vaccination schedules and perinatal care. These strategies have demonstrated positive impacts in regions affected by conflict, forced migration, and extreme poverty, although challenges related to sustainability and equity persist [29,55].

Cluster 3 highlights the profound interrelationships between HIV, vaccines, and maternal-infant immunological health within contexts of high vulnerability. The gathered evidence supports the urgency of public health policies that combine biomedical innovation, social justice, and community engagement to ensure the right to health for mothers and children in adverse conditions.

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Cluster 4: Biological Therapies and Immunometabolic and Perinatal Impact in Women with Chronic Diseases.

This cluster focuses on research related to the use of biological therapies in women with chronic immunological diseases and their association with immunotoxic adverse effects, metabolic disorders, and perinatal risks. The role of drugs such as etanercept, anti-TNF agents, and vitamin D is highlighted, along with their potential side effects on immune function, metabolism, and reproductive and fetal health. The approach combines elements of clinical immunology, pharmacovigilance, endocrinology, and maternal health (see Figure 5).

Cluster 4 encompasses research focused on the use of biological therapies for the treatment of chronic diseases in women of reproductive age, particularly exploring their effects on the immunometabolic system and perinatal outcomes. The literature grouped within this cluster reflects a growing interest in understanding how immunological modulation induced by biotechnological agents such as TNF inhibitors, interleukins, or monoclonal antibodies influences maternal metabolic health, placental function, and fetal development [56,57].
A common finding in the studies is the need to balance the therapeutic benefits of these interventions with their potential risks during pregnancy. Diseases such as systemic lupus erythematosus, rheumatoid arthritis, Crohn's disease, and multiple sclerosis require strict immunological control to prevent exacerbations that could endanger both the mother and the fetus. However, the side effects of biological therapies, including alterations in maternal immune tolerance and carbohydrate and lipid metabolism, raise questions about their safety during gestation [58–60].

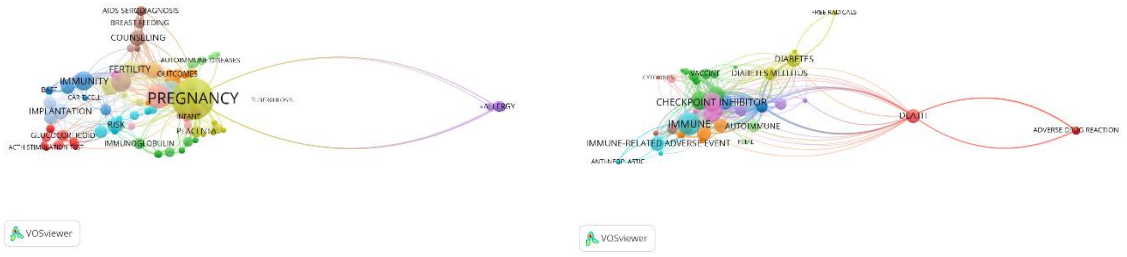
The cluster also highlights studies reporting complications such as gestational diabetes, preeclampsia, intrauterine growth restriction, and preterm birth in women exposed to immunomodulators. These manifestations may be related to changes in inflammatory signaling and the immunoendocrine axis induced by treatments, as well as complex pharmacological interactions between biotherapy and the physiological adaptations of pregnancy [61–63]. Nonetheless, some studies also emphasize the importance of not indiscriminately discontinuing these treatments, as uncontrolled maternal disease activity poses a greater risk to perinatal outcomes than the potential effects of the drug.

Another recurrent aspect in the studies is the analysis of transplacental effects of biological therapies. Various investigations have documented the placental transfer of monoclonal antibodies and their presence in fetal circulation, raising implications for neonatal immune response and long-term metabolic programming. Consequently, specialized pediatric follow-up is recommended for children of mothers treated during pregnancy, particularly during the first months of life when the neonatal immune system is still maturing [64–66].

Finally, the cluster emphasizes the need for multidisciplinary approaches in managing women with chronic diseases requiring biological therapies. Coordination among rheumatologists, gastroenterologists, immunologists, endocrinologists, and obstetricians is essential for informed clinical decision-making, therapeutic regimen adjustments, and minimizing immunometabolic and perinatal risks. In this regard, clinical guidelines should be continuously updated, incorporating new evidence on pharmacokinetics, teratogenicity, and long-term impact.

Figure 5. CO-OCCURRENCE NETWORK OF EACH CLUSTER

Cluster 1 Cluster 2



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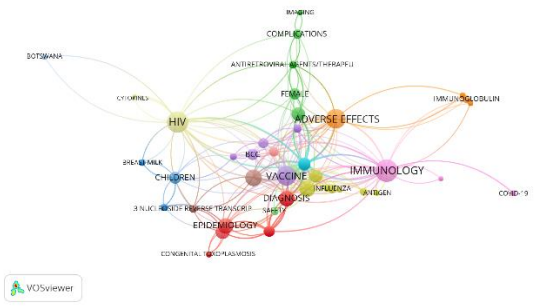
Cluster 3



Cluster 4

CONCLUSIONS

This study provides a comprehensive and well-founded perspective on the intersection of women, immunology, and adverse effects of pharmacological therapies, highlighting a research field in full development that has historically been underrepresented in biomedical literature. Using a rigorous bibliometric approach grounded in the PRISMA methodology and co-occurrence term analysis, the main trends, gaps, and thematic clusters defining the current state of knowledge in this critical area of medicine were systematically mapped.

The findings demonstrate that women exhibit greater susceptibility to immunological adverse effects, explained by particular physiological, hormonal, and immunogenetic characteristics. This heightened reactivity manifests diversely in clinical contexts such as oncological immunotherapy, vaccination in women with autoimmune diseases, pregnancy, lactation, and the use of biological therapies during reproductive age. Consequently, the evidence underscores the urgent need to incorporate a gender perspective in clinical research, therapeutic trials, and pharmacovigilance strategies.

Co-occurrence network analysis identified four relevant thematic clusters: reproductive immunoregulation, immunotherapy with metabolic impact, maternal-infant immunological health in vulnerable contexts, and perinatal immunometabolic effects from biological therapies. Each of these clusters reveals specific issues requiring interdisciplinary and personalized approaches, supported by sex-disaggregated data, immunological biomarkers, and reproductive clinical considerations.

Moreover, the application of bibliometric tools combined with qualitative and clinical analyses enables the identification of research patterns, emerging trends, and pending challenges, representing a valuable contribution to evidence-based medicine and public health decision-making.
In summary, this study not only confirms the existence of a kno
wledge gap regarding immunological adverse effects in women but also proposes a methodological and conceptual framework to address this historical omission. Advancing toward more equitable, safe, and personalized medicine entails recognizing the immunological particularities of the female sex, adapting therapies to their specific needs, and ensuring that women are regarded as central subjects in the generation and application of biomedical knowledg.

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