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Original article

Autoimmune Liver Diseases in Mexico: Clinical Characterization and Outcomes at a National Referral Center (2012–2022)

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Abstract

Introduction: Autoimmune liver diseases, including autoimmune hepatitis (AIH), primary biliary cholangitis (PBC), and primary sclerosing cholangitis (PSC), are uncommon, exhibit heterogeneous phenotypes, and remain poorly characterized in Latin American populations. **Objective:** To describe the clinical and sociodemographic characteristics, as well as the outcomes, of patients with confirmed diagnoses of AIH, PBC, and PSC treated at a national referral center in Mexico between 2012 and 2022. **Materials and methods:** A descriptive, cross-sectional observational study using secondary data sources was conducted. Adults with a confirmed diagnosis of autoimmune liver disease were included. Clinical, serological, and outcome variables were analyzed using descriptive statistics with Stata v.17. **Results:** A total of 303 patients were analyzed, of whom 77.9% were women, with a mean age of 50 years. Diagnoses included AIH (78.9%), PBC (46.5%), and PSC (8.2%), with 98 cases of overlap syndromes (AIH–PBC: 93; AIH–PSC: 7). The most frequent comorbidities were overweight, hypothyroidism, dyslipidemia, and ulcerative colitis. Treatment response was higher in PBC (88.6%) and AIH (84.9%), whereas PSC showed a greater need for transplantation (68%) and recurrence (100%). **Conclusions:** In this center, AIH was the most frequent entity, followed by PBC and PSC, with a considerable number of overlap syndromes, the most common being AIH–PBC. More favorable outcomes were observed in AIH and PBC, whereas PSC showed poorer clinical evolution. These findings provide relevant regional evidence and underscore the need for multicenter studies on autoimmune liver diseases in Latin America.

Keywords

Autoimmune hepatitis; primary biliary cholangitis; primary sclerosing cholangitis.

INTRODUCTION

Autoimmune liver diseases comprise a spectrum of potentially progressive idiopathic inflammatory disorders that are classically described in three clinical presentations: primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), characterized by a predominantly cholestatic pattern of injury, and autoimmune hepatitis (AIH), characterized by predominantly hepatocellular injury, as well as overlap syndromes among these entities[1–3]. In recent years, other immune-mediated disorders have been proposed for inclusion within this spectrum, such as immunoglobulin G4-associated sclerosing cholangitis (IgG4-SC), and it has been suggested that some cases previously classified as PSC may actually correspond to this entity[1,4–6].

Significant changes in the epidemiology of these diseases have been described in recent years. In different regions of the world, an increase in the incidence and prevalence of autoimmune liver diseases has been observed, particularly for AIH and PSC in Europe and North America,

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whereas PBC has shown an increase in prevalence across various regions, including Asia and the Americas[1,2,7–9]. Population-based studies and multicenter cohorts have improved our understanding of the clinical course experienced by patients, highlighting variations in disease presentation according to geographic, demographic, and temporal factors[10,11]. The diagnosis of these diseases requires the integration of clinical, immunologic, radiologic, and histopathologic findings, reflecting the complexity of their clinical presentation and the heterogeneity of their phenotypes. In addition, some patients may present with overlap syndromes, in which features of more than one of these entities coexist, representing a diagnostic and therapeutic challenge in clinical practice[1,3,12].

Although autoimmune liver diseases are uncommon, they share the characteristic of imposing a high clinical burden relative to the incidence and prevalence of each condition in the population[10]. These disorders are characterized by phenotypic presentations that vary according to age, sex, and geographic context, variables that also influence clinical response and disease progression[1–3,13]. Autoimmune hepatitis (AIH) is a heterogeneous disease with two clinical forms: type 1 AIH, which affects both children and adults and is characterized by elevated antinuclear antibodies (ANA) and anti-smooth muscle antibodies (anti-SMA), and type 2 AIH, which is associated with positivity for liver kidney microsomal type 1 antibodies (anti-LKM1) and, in some cases, anti-liver cytosol type 1 antibodies (anti-LC1) [5,14–16]. Its estimated incidence is 1 case per 100,000 inhabitants per year, with a predominance in women[17–19].

Primary sclerosing cholangitis (PSC) exhibits a broad clinical spectrum, ranging from asymptomatic cases to presentations with jaundice, pruritus, hepatomegaly, or splenomegaly[1,20,21]. Its prognosis has been associated with age, liver function, and the presence of inflammatory bowel disease[2,5,22], with a mortality rate three times higher than that of the general population[17,23]. Primary biliary cholangitis (PBC), formerly known as *primary biliary cirrhosis*, is defined by injury to the small- and medium-sized intrahepatic bile ducts, positivity for antimitochondrial antibodies (AMA-M2) in 90% of cases, and a predominance in women between 30 and 60 years of age[16,24]. Its diagnosis requires at least two of the following three criteria: positive AMA, elevated alkaline phosphatase for more than six months, and chronic cholangitis involving the intrahepatic bile ducts[3,15,25]. Overlap syndromes may be observed in all of these entities, particularly AIH-PBC overlap and, less frequently, overlap between PBC and PSC[3,4,17,20,26].

In Latin America, although the available information remains limited compared with other regions, several clinical series and cohort studies published in recent years have described the epidemiology and clinical characteristics of autoimmune liver diseases. In Mexico, for example, an approximate prevalence of 8.5% of these diseases has been reported in liver biopsy-based studies and up to 17% in cohorts of patients with cirrhosis, underscoring the growing relevance of these disorders in the region[27]. In addition, some studies have reported a high proportion of cirrhosis at the time of diagnosis among Latin American patients, suggesting delayed diagnosis and highlighting the need for better characterization of these diseases in regional populations. In Mexico, the published evidence remains relatively limited and is restricted primarily to studies with small sample sizes. A descriptive study conducted at the ISSEMyM Medical Center characterized the clinical features of 78 patients with primary biliary cholangitis treated between 2005 and 2012[23]. However, the available evidence remains fragmentary and derives mainly from single-center studies, limiting the understanding of the clinical behavior, comorbid associations, and outcomes of these disorders in Latin American populations[27,28].

In this context, the aim of the present study was to characterize the clinical and sociodemographic profile, as well as the outcomes, of patients diagnosed with AIH, PSC, and PBC who were treated at a national referral center in Mexico during the period from 2012 to 2022.

MATERIALS AND METHODS

A descriptive cross-sectional observational study was conducted using secondary data from patients diagnosed with autoimmune hepatitis (AIH), primary sclerosing cholangitis (PSC), and primary biliary cholangitis (PBC) who were treated at the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, a national clinical referral center in Mexico, between 2012 and 2022. All adult patients with a confirmed diagnosis of AIH, PSC, or PBC who were treated at the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán during the study period were included. This population was characterized based on data extracted from the medical records in order to describe and analyze sociodemographic and clinical variables relevant to understanding these diseases in the Latin American context.

The diagnosis of AIH was established according to the criteria proposed by the International Autoimmune Hepatitis Group (IAIHG), considering both the original and simplified criteria, which integrate clinical, serological, and histopathological findings when available. PBC was diagnosed based on the presence of positive antimitochondrial antibodies (AMA) and persistent elevation of alkaline phosphatase, or on compatible histopathological findings. PSC was diagnosed based on characteristic cholangiographic findings and the exclusion of secondary causes of cholangiopathy[29,30]. In all cases, the diagnosis was esta-

blished by hepatology or gastroenterology specialists at the Institute and recorded as a confirmed diagnosis in the institutional medical record. Response to treatment was defined based on the clinical and biochemical improvement documented in the medical records, including normalization or a significant reduction in transaminase levels and cholestatic markers according to the underlying disease.

Information on sociodemographic and clinical variables was collected from the medical records of patients treated during the study period who had confirmed autoimmune liver disease, as documented in the medical record. A detailed descriptive analysis of the data was performed to obtain information on the distribution and characteristics of the variables. Measures of central tendency, frequencies, and proportions were calculated according to the type of variable, and the information was classified for each liver disease. Stata version 17 was used for the analysis.

RESULTS

Data from 303 individuals were analyzed, of whom 236 (77.89%) were female. The mean age was 50.03 ± 13.50 years (range: 21 to 77 years), and 52.15% belonged to the middle socioeconomic level. The sociodemographic characteristics of the sample are presented in **Table 1**.

Among the 303 patients included, 239 cases of autoimmune hepatitis (AIH) (78.88%), 25 cases of primary sclerosing cholangitis (PSC) (8.25%), and 141 cases of primary biliary cholangitis (PBC) (46.53%) were identified. Due to the presence of overlap syndromes, some patients were classified into more than one diagnostic category. A total of 98 overlap syndrome cases were identified. Of these, seven corresponded to AIH-PSC overlap (2.31% of all cases), 89 to AIH-PBC overlap (29.37% of all cases), and two to PSC-PBC overlap (0.66% of all cases). Regarding diagnostic confirmation, histopathological confirmation by liver biopsy was available in 232 of the 239 patients with autoimmune hepatitis (97.1%), whereas in the remaining cases the diagnosis was established based on clinical, serological, and imaging criteria. In the overall cohort, 96.0% of patients underwent histopathological liver evaluation, reflecting the diagnostic approach at this referral center based on clinicopathologic correlation.

The medical histories identified in the patients are described according to the diagnosed autoimmune disease in **Table 2**. The most frequent comorbidities among patients diagnosed with AIH were overweight (45.19%), dyslipidemia (20.50%), hypothyroidism (20.50%), diabetes *mellitus* (19.25%), and arterial hypertension (16.74%). Among patients diagnosed with PSC, the most frequent conditions were ulcerative colitis (80%), pancreatitis (40%), underweight (26%), depression (24%), overweight (20%),

Table 1. Sociodemographic Characteristics of Patients Diagnosed with Autoimmune Liver Diseases

Variable	n	%
Sex		
Male	67	22.11
Female	236	77.89
Socioeconomic Level		
High	37	12.21
Middle	158	52.15
Low	107	35.31
Missing data	1	0.33
Marital Status		
Single	82	27.06
Married	162	53.47
Common-Law Marriage	15	4.95
Divorced	28	9.24
Widowed	15	4.95
Missing data	1	0.33
Education Level		
Illiterate	1	0.33
Primary school	34	11.22
Secondary school	143	47.19
High school	1	0.33
Technical education	21	6.93
University	95	31.35
Postgraduate	4	1.32
Missing data	4	1.32
Occupation		
Homemaker	95	31.35
Retired	31	10.23
Salesperson	31	10.23
Unemployed	26	8.58
Bachelor's degree holder	16	5.28
Student	12	3.96
Secretary	9	2.97
Other occupations	80	26.40
Missing data	3	0.99
Religion		
Catholic	282	93.07
Evangelical	6	1.98
Agnostic	3	0.99
Jehovah's Witness	3	0.99
None	9	2.97

Author's own research.

and a family history of autoimmune disease (20%). In contrast, among patients with PBC, the most commonly reported conditions were overweight (49.65%), hypothyroidism (28.37%), Sjögren's syndrome (18.44%), underweight (16.31%), and dyslipidemia (15.60%).

With respect to clinical laboratory findings, the most representative results were antinuclear antibodies (ANA) and antimitochondrial antibodies (AMA). Regarding overlap syndromes, these were most frequent in primary biliary cholangitis, with a prevalence of 52.55%. AMA positivity was identified in 65 (29.55%) cases of autoimmune hepatitis, which may correspond to those associated with overlap with primary biliary cholangitis.

Among liver function test findings, autoimmune hepatitis showed a predominantly hepatocellular pattern, with greater elevations in aspartate aminotransferase (AST) levels (range: 0.56–4,086) than in alanine aminotransferase (ALT) levels (range: 0.44–2,664), as well as greater alterations in immunoglobulin G (range: 235–7,824) and immunoglobulin M (range: 65–2,252) levels. In primary biliary cholangitis, a mixed pattern of hepatocellular and cholestatic injury predominated, with more marked abnormalities in γ-glutamyl transferase (GGT) levels (range: 26–7,093).

Regarding patient outcomes, the highest treatment response rates were observed in patients with primary biliary

Table 2. Medical History of Patients According to the Diagnosed Autoimmune Liver Disease

Medical History	Autoimmune Hepatitis (n = 239)		Primary Sclerosing Cholangitis (n = 25)		Primary Biliary Cholangitis (n = 141)	
	n	%	n	%	n	%
Systemic lupus erythematosus	31	12.97	0	0	14	9.93
Autoimmune thyroiditis	5	2.09	1	4.00	2	1.42
Hypothyroidism	49	20.50	1	4.00	40	28.37
Arterial hypertension	40	16.74	2	8.00	15	10.64
Diabetes *mellitus*	46	19.25	2	8.00	12	8.51
Rheumatoid arthritis	8	3.35	1	4.00	6	4.26
Ulcerative colitis	9	3.77	20	80.00	4	2.84
Crohn's disease	0	0	0	0	0	0
Celiac disease	1	0.42	1	4.00	0	0
Sjögren's syndrome	18	7.53	1	4.00	26	18.44
Sicca syndrome	7	2.93	0	0	7	4.96
Scleroderma	15	6.28	0	0	21	14.89
Dermatomyositis	3	1.26	0	0	1	0.71
Psychiatric disorder	28	11.72	7	28.00	18	12.77
Depression	21	8.79	6	24.00	15	10.64
Anxiety	10	4.18	1	4.00	7	4.96
Normal weight	60	25.10	10	40.00	32	22.70
Underweight	34	14.23	9	36.00	23	16.31
Overweight	108	45.19	5	20.00	70	49.65
Obesity	34	14.23	1	4.00	16	11.35
Dyslipidemia	49	20.50	0	0	22	15.60
Alcohol consumption	10	4.18	0	0	2	1.42
Use of hepatotoxic medications	6	2.51	0	0	1	0.71
Smoking	14	5.86	0	0	5	3.55
Family history of autoimmune disease	12	5.02	5	20.00	4	2.84
Cytomegalovirus infection	11	4.60	1	4.00	4	2.84
Tuberculosis	6	2.51	0	0	1	0.71

Author's own research.

cholangitis and autoimmune hepatitis, at 89.05% and 84.94%, respectively. Remission was achieved in 74.48% of patients with autoimmune hepatitis, and recurrence occurred in 100% of patients with primary sclerosing cholangitis. Chronic hepatitis was present in more than 80% of patients across all three clinical forms of autoimmune liver disease. In addition, a substantial proportion of patients developed osteoporosis, and the need for liver transplantation was greatest among patients with primary sclerosing cholangitis (68%). Both acute and chronic transplant rejection were frequent in patients with autoimmune hepatitis, occurring in 25.45% and 21.82% of cases, respectively (**Table 3**).

DISCUSSION

This study, conducted at a national referral center in Mexico, represents one of the largest Latin American series on autoimmune liver diseases (AIH, PBC, and PSC). Our results confirm that AIH is the most frequent entity, followed by PBC and PSC, with a considerable proportion of overlap syndromes, mainly AIH-PBC overlap. This distribution is consistent with reports from other regions, where AIH represents the most common form within the spectrum of autoimmune liver diseases, particularly in Western populations[1–3,7,8,31]. Likewise, recent studies have reported a progressive increase in the incidence and prevalence of these disorders in different regions of the world, attributed both to improved diagnostic detection and to environmental and immunologic changes[7,8]. In Latin America, recent reviews have highlighted that the available evidence remains limited and derives mainly from clinical series from referral centers, making it difficult to establish comparable regional epidemiologic patterns[27,28].

Most cases corresponded to AIH, followed by PBC and PSC, with greater involvement of women in AIH and PBC, and of men in PSC, similar to what has been reported in the international literature. This sex-related difference is consistent with international studies demonstrating differences in presentation and prognosis according to sex, particularly in primary biliary cholangitis[16,24]. Overlap syndrome was observed, and the most frequent phenotype was PBC-AIH overlap, followed by AIH-PSC overlap, also in agreement

Table 3. Outcomes in Patients According to the Diagnosed Autoimmune Liver Disease

Medical History	Autoimmune Hepatitis (n = 239)		Primary Sclerosing Cholangitis (n = 25)		Primary Biliary Cholangitis (n = 141)	
	n	%	n	%	n	%
Treatment response	203	84.94	17	68.00	125	88.65
Remission	178	74.48	12	48.00	91	64.54
Recurrence	160	66.95	25	100	113	80.14
Chronic hepatitis	200	83.68	25	100	129	91.49
Cirrhosis	96	40.17	15	60.00	63	44.68
Liver failure	58	24.27	6	24.00	25	17.73
Osteoporosis	109	45.61	4	16.00	44	31.21
Need for transplantation	74	30.96	17	68.00	54	38.30
Acute transplant rejection	14	25.45	1	7.14	5	13.51
Chronic transplant rejection	12	21.82	0	0	4	10.53
Recurrence of autoimmune disease after transplantation	22	40.00	2	13.33	21	55.26
Hepatocellular carcinoma	3	1.26	1	4.00	2	1.43
Cholangiocarcinoma	0	0	0	0	0	0
Other cancers	1	0.42	1	4.00	1	0.71
Death	19	7.95	3	12.00	15	10.64

Author's own research.

with findings reported in the literature[3,4,17,20,26]. Patients with overlap syndrome were predominantly women and exhibited lower treatment response rates and more episodes of disease reactivation, as previously reported[1,17,21].

Regarding outcomes, the best treatment response and remission rates were observed in AIH and PBC, whereas PSC showed the greatest need for transplantation and the highest recurrence rates, consistent with international reports describing PSC as the entity with the poorest prognosis[14,17,18,21,32]. A relevant finding was the frequency of post-transplant rejection in patients with AIH, which raises questions regarding the difficulty of differentiating between disease recurrence and immunologic rejection. This issue has been highlighted in previous studies and underscores the need for meticulous clinicopathologic evaluation in this subgroup of patients[19,21]. Some authors have emphasized the importance of intrinsic donor characteristics, their associated risks, and the true presence of rejection or disease recurrence. This is particularly relevant in PSC cases, in which stenotic lesions of the biliary tract may be observed and can lead to confusion with ischemic cholangiopathy, disease recurrence, or rejection, making it difficult to determine whether the findings overlap or are associated with recurrence of the underlying disease[1,10,21].

These disorders are also well known to be associated with other autoimmune diseases, with coexistence reported in up to 20% of patients. Some of the autoimmune conditions associated with these disorders include systemic lupus erythematosus, autoimmune thyroiditis, hypothyroidism, rheumatoid arthritis, and inflammatory bowel disease. The latter is more strongly associated with PSC and contributes to disease recurrence and the need for transplantation, in addition to increasing the risk of developing colon cancer and cholangiocarcinoma[12,20,21,31,33]. In our study, a high prevalence of osteoporosis was observed, particularly in AIH, probably related to chronic corticosteroid use, disease recurrence, and the coexistence of other rheumatologic diseases[5]. This finding reinforces the importance of implementing prevention and follow-up programs for metabolic complications in this population[22,23].

Histopathologic findings continue to be of major importance for the clinicopathologic correlation of these disorders, especially in AIH and PBC, in which they may be decisive in guiding the diagnosis in some cases[34]. The predominant findings included interface hepatitis, lymphoplasmacytic infiltrates, and lobular involvement in AIH, whereas the presence of portal granulomas and bile duct injury suggested PBC involvement. Interpretation becomes more complex when a combination of these findings is observed, suggesting the diagnosis of overlap syndrome, which must always be corroborated with clinical findings. In only four cases, submassive hepatic parenchymal necrosis associated with acute liver failure and interface hepatitis was identified, suggesting AIH involvement, and two of these patients required transplantation. In this regard, the high proportion of histopathologic confirmation in our cohort strengthens the clinicopathologic correlation and constitutes an important diagnostic strength of the study.

Among the strengths of our study are the considerable sample size and the focus on a Mexican cohort, which remains underrepresented in the international literature. Recent studies have highlighted that autoimmune liver diseases represent a growing burden on healthcare systems in Mexico and other Latin American countries, particularly because of their chronic course, the need for prolonged immunosuppression, and the risk of progression to cirrhosis or liver transplantation[27,28]. In this regard, the findings of the present study contribute to expanding the available evidence in the region and to improving the understanding of the clinical profile and outcomes of these disorders in Latin American populations.

Among the identified limitations was the lack of information regarding the initial diagnosis and management of some patients, several of whom were referred in advanced stages of disease due to the need for inclusion in the liver transplantation program, or had been diagnosed during childhood and were referred to the Institute upon reaching adulthood. It should also be acknowledged that the Institute where the present study was conducted exclusively manages adult patients. Future studies should include the pediatric population, given the interest in phenotyping these diseases in this age group, in which greater variability has been described in the international literature[35]. Likewise, because of the retrospective nature of the study and the use of secondary clinical records, it was not possible to establish the follow-up time uniformly for all patients, which limits estimation of the cohort's median follow-up time. Finally, as this is a national referral center, the cohort likely includes a greater proportion of complex or advanced disease cases.

It is important to note that additional studies conducted in greater depth are needed to establish associations with the identified variables, as well as to further characterize the phenotypes of the Mexican population in order to improve understanding of autoimmune liver disease and thereby guide treatment and improve patient survival.

CONCLUSIONS

This study, conducted at a national referral center in Mexico, enabled the identification of the main clinical and epidemiologic characteristics of patients with autoimmune liver diseases over a 10-year period. Autoimmune hepatitis was the most frequent entity, followed by primary biliary cholangitis

and primary sclerosing cholangitis, with a relevant number of overlap syndromes, particularly AIH-PBC overlap.

Treatment response and remission rates were more favorable in AIH and PBC, whereas PSC showed a poorer prognosis, with greater recurrence and need for transplantation. These findings contribute to expanding knowledge regarding the clinical behavior of autoimmune liver diseases in the Latin American population and highlight the importance of continuing to develop regional studies that allow for a better understanding of their progression and optimization of management strategies.

Ethical Considerations

This research followed the principles of the Declaration of Declaration of Helsinki and the Belmont Report for research involving human subjects, as well as the Mexican Official Standard NOM-004-SSA3-2012 regarding medical records, emphasizing that "the information reviewed in the medical record shall be handled with discretion and confidentiality," and no personal data were published or disclosed. The study was considered research without biological, psychological, physiological, or social risk for the patients of the Institution, since the information was collected through anonymized secondary data and no individual-level intervention representing risk to the integrity of the study. The project was approved by the Research and Ethics Committee of the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán.

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Conflict of Interest

The authors declare that there were no conflicts of interest in the conduct of the present study.

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