Incidence and Prevalence of Primary Biliary Cholangitis and Cholestatic Pruritus in Germany: Results from a Statutory Health Insurance Claims Analysis

Digital poster
Supplemental data
Narrated summary

SCAN ME

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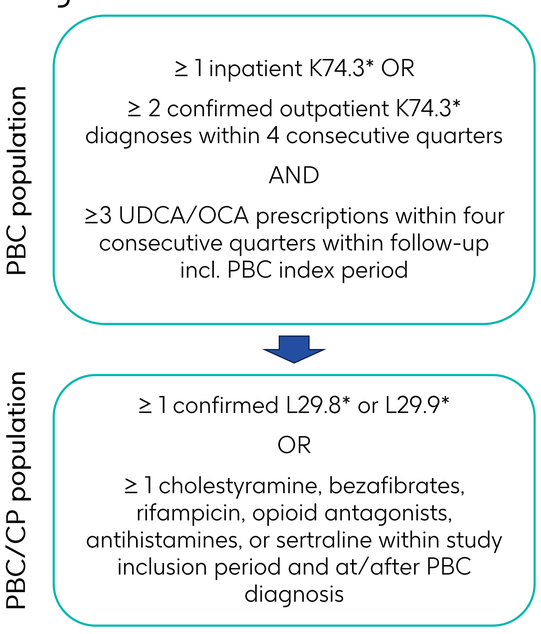
Introduction

- Primary biliary cholangitis (PBC) is an autoimmune liver disease characterized by progressive destruction of intrahepatic bile ducts, resulting in cholestasis, cirrhosis, and portal hypertension. Cholestatic pruritus (CP) affects approximately 60% to 81% of PBC patients [1.2].
- No new pharmacologic treatments for CP have been introduced since the 1960s. Ursodeoxycholic acid (UDCA), the standard therapy for PBC, does not alleviate CP. Cholestyramine and, more recently, bezafibrate are considered first-line treatments; alternatives such as rifampicin, opioid antagonists, antihistamines, and sertraline show limited long-term efficacy and are associated with adverse effects [3.4].
- Data on epidemiology and treatment of CP in Germany are scarce, underscoring the need for comprehensive investigation.

Methods

- **Data**: Anonymized claims data from approximately 7 million German SHI patients covering the period 2013–2022 were analyzed. The dataset includes outpatient and inpatient care, prescriptions, diagnoses, demographics, and costs.
- **Study Period**: Patients required at least 4 quarters of look-back period for study inclusion. For incidence and prevalence calculation, patients had to be SHI enrolled at least 4 quarters before and after index date. For treatment analyses, patients needed to have at least 8 quarters of follow-up after index date.

Figure 1: Selection Flowchart

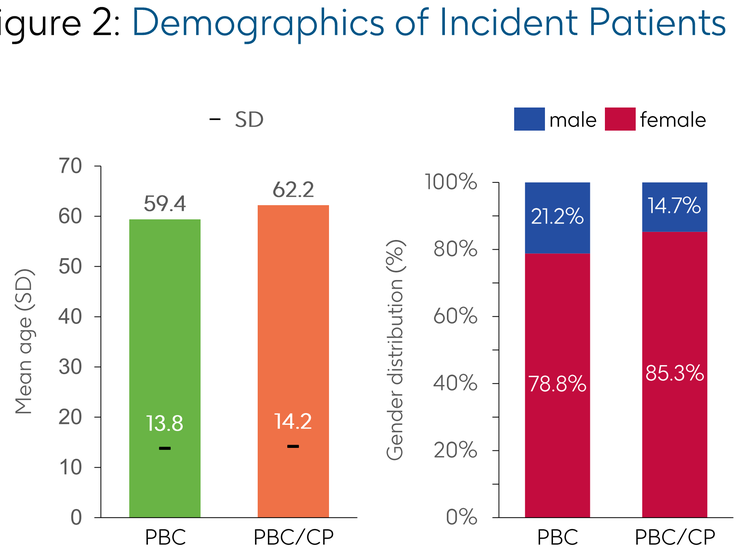


- **Index date:** For PBC patients: 1st diagnosis date; for PBC patients with CP: 1st pruritus diagnosis or 1st relevant prescription at/after PBC diagnosis.
- **Incidence and prevalence proportions**: Proportion of incident/prevalent patients relative to patients at risk
- **Incidence and prevalence rates:** Projected patient numbers relative to the German SHI population (by 100,000)
- **PBC diagnosis** was carried forward to reflect the chronic nature of the disease, while the **CP diagnosis** had to be re-established each calendar year, since symptoms can be waning over time. Only the first CP diagnosis was labelled incident for PBC patients with CP.
- **Projection**: Incidence and prevalence rates, as well as total patient counts, were scaled through direct adjustment based on age- and gender-specific distributions from official statistics of the German SHI population.

**ICD-GM-10*

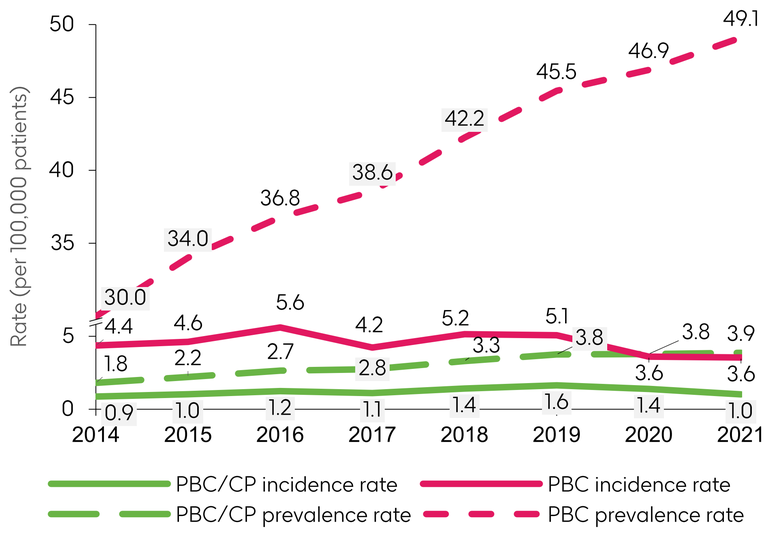
Results

Figure 2: Demographics of Incident Patients



- Mean age of incident PBC patients with CP is ~2 years higher compared to PBC patients without records of CP
- Proportion of newly diagnosed female patients is higher in PBC patients with CP (85.3%) as compared to PBC patients without records of CP (78.8%.)

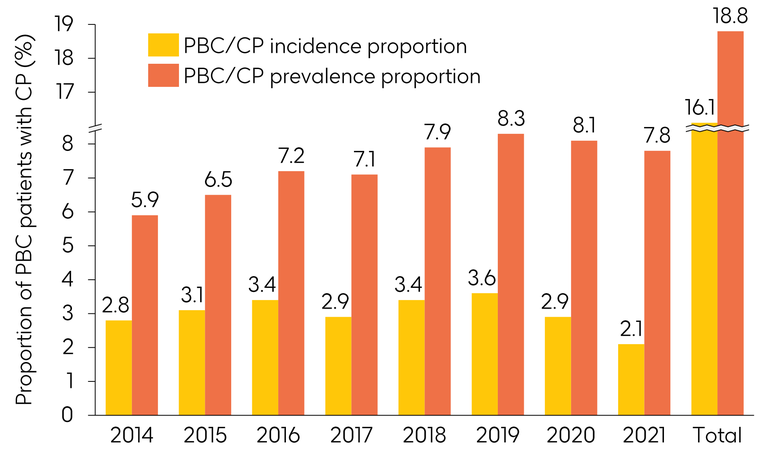
Figure 3: PBC and PBC/CP Incidence and Prevalence Rates



Incidence and prevalence rates for PBC and PBC/CP patients were calculated using the SHI dataset (~7 million patients) and projected to the full German SHI population (~90% coverage).

- PBC incidence ranged from 3.6 to 5.6/100,000 patients annually
- PBC prevalence per 100,000 increased 1.6-fold from 2014 to 2021
- The incidence rate of PBC patients with CP amongst the SHI population ranged from 0.87 to 1.64 annually
- The prevalence of PBC patients with CP rose slightly between 2014 and 2020, with 1–2 new cases per 100,000 annually

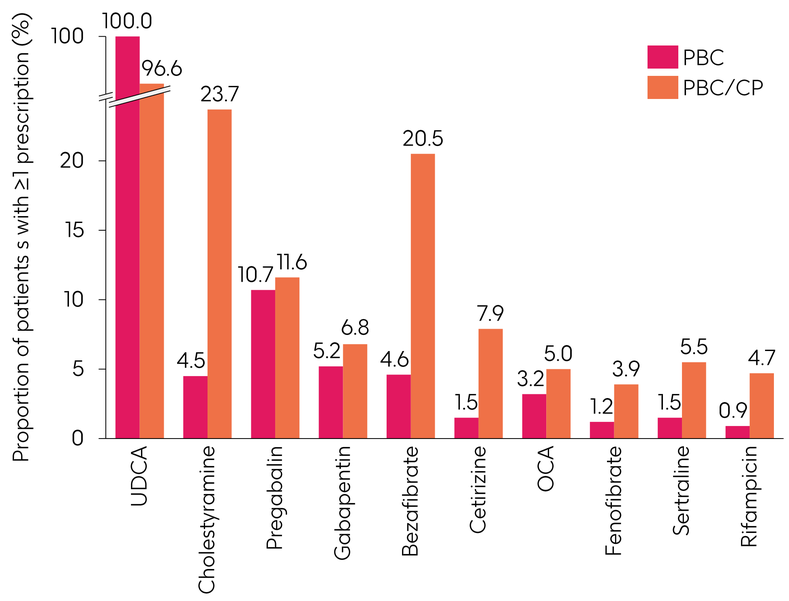
Figure 4: CP Incidence and Prevalence Amongst PBC Patients over Time



Incidence and prevalence proportions for CP within the PBC population.

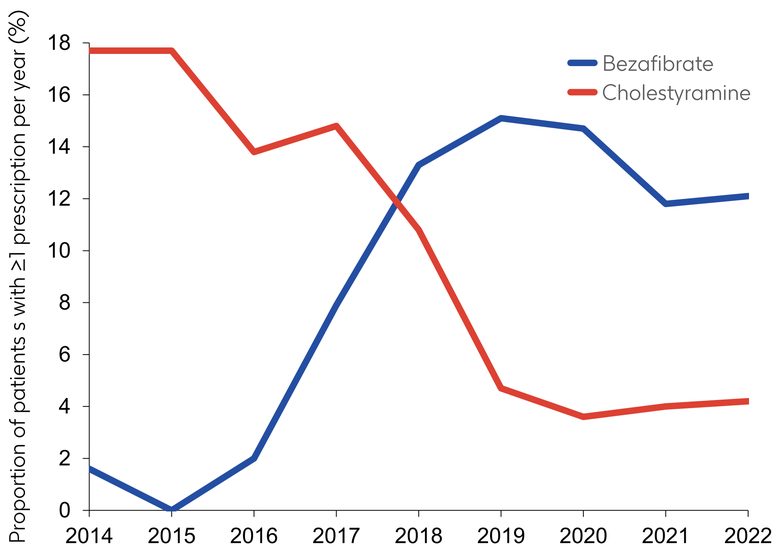
- In this sample of SHI-insured patients in Germany, 8-year PBC/CP prevalence was ~19%.
- The 8-year prevalence rates were comparable amongst older and younger PBC patients (<65 years: 17%; ≥65 years: 17).

Figure 5: Top 10 Treatments, 2014-2022



- Amongst the potential CP medications, the top three were cholestyramine, bezafibrate, as well as pregabalin
- However, only 23.7% of PBC patients with records of CP received cholestyramine, even though German guidelines recommend it as first-line therapy for CP throughout the study period

Figure 6: Time Trends in Cholestyramine or Bezafibrate Prescriptions in PBC patients with CP



- Cholestyramine use in PBC patients with CP declined from 17.7% in 2014 to 4.2% in 2021, while the proportion of patients with at least one prescription of bezafibrate increased from 1.6% to 11.8% during this timeframe

Conclusions

- PBC prevalence is rising; CP is a relevant symptom amongst PBC patients
- Current CP treatments are underutilized, with only a small patient fraction receiving therapy.
- The use of the only approved drug for the treatment of CP, cholestyramine, declined drastically over time
- The increasing burden on patients and the healthcare system indicates a need for therapeutic innovation.

Abbreviations

PBC = Primary Biliary Cholangitis
CP = Cholestatic Pruritus
UDCA = Ursodeoxycholic acid
OCA = Obeticholic acid

References

1 Patel, S.P.; Vasavda, C.; Ho, B.; Meixiong, J.; Dong, X.; Kwatra, S.G. Cholestatic Pruritus: Emerging Mechanisms and Therapeutics. *J Am Acad Dermatol* **2019**, *81*, 1371–1378, doi:10.1016/j.jaad.2019.04.035.
2 Mayo, M.J.; Carey, E.; Smith, H.T.; Mospan, A.R.; McLaughlin, M.; Thompson, A.; Morris, H.L.; Sandefur, R.; Kim, W.R.; Bowlus, C.; et al. Impact of Pruritus on Quality of Life and Current Treatment Patterns in Patients with Primary Biliary Cholangitis. *Dig Dis Sci* **2023**, *68*, 995–1005, doi:10.1007/s10620-022-07581-x.
3 European Association for the Study of the Liver Available online: https://easl.eu/ (accessed on 18 January 2024).
4Ständer S. et al. S2k-Leitlinie zur Diagnostik und Therapie des chronischen Pruritus. 2022. https://www.awmf.org/leitlinien/detail/ll/013-048.html

Acknowledgements

This study was funded by GSK.

Disclosures

LW, VS and SH are employees of GSK.
CV and SD are paid employees of IQVIA. CV was a paid consultant to the National Institutes of Mental Health (US). AW is a paid employee of Team Gesundheit.