

Burden of disease of Primary Sclerosing Cholangitis: A Retrospective Cohort Study in Germany

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OBJECTIVES

- Primary Sclerosing Cholangitis (PSC) is a rare cholestatic liver disease characterized by inflammation and scarring (fibrosis) of the intra- and extrahepatic bile ducts.
- This study investigates prevalence, incidence, treatment as well as burden and costs of PSC in Germany.

METHODS

Data source:

- This retrospective cohort study utilized German claims data from the Statutory Health Insurance (SHI) database, specifically the 'German Analysis Database' (Deutsche Analysedatenbank für Evaluation und Versorgungsforschung - DADB).
- At the start of analysis, the DADB contained approximately 4.1 million individuals in 2013-2022 representing a 5% sample of the German SHI population.

Analyses:

- We focused on patients diagnosed with PSC (ICD-10-GM code K83.00; available since 2022) in the year 2022, assessing both prevalence and incidence rates.
- The study identified the usage of procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and medication (i.a. ursodeoxycholic acid (UDCA)).
- Additionally, we evaluated comorbidities and health care resource utilization (HCRU) costs, comparing these findings to an age and gender-matched control group.
- Results were age- and gender adjusted extrapolated to the overall German SHI including 75,067,416 persons (Fig. 1).

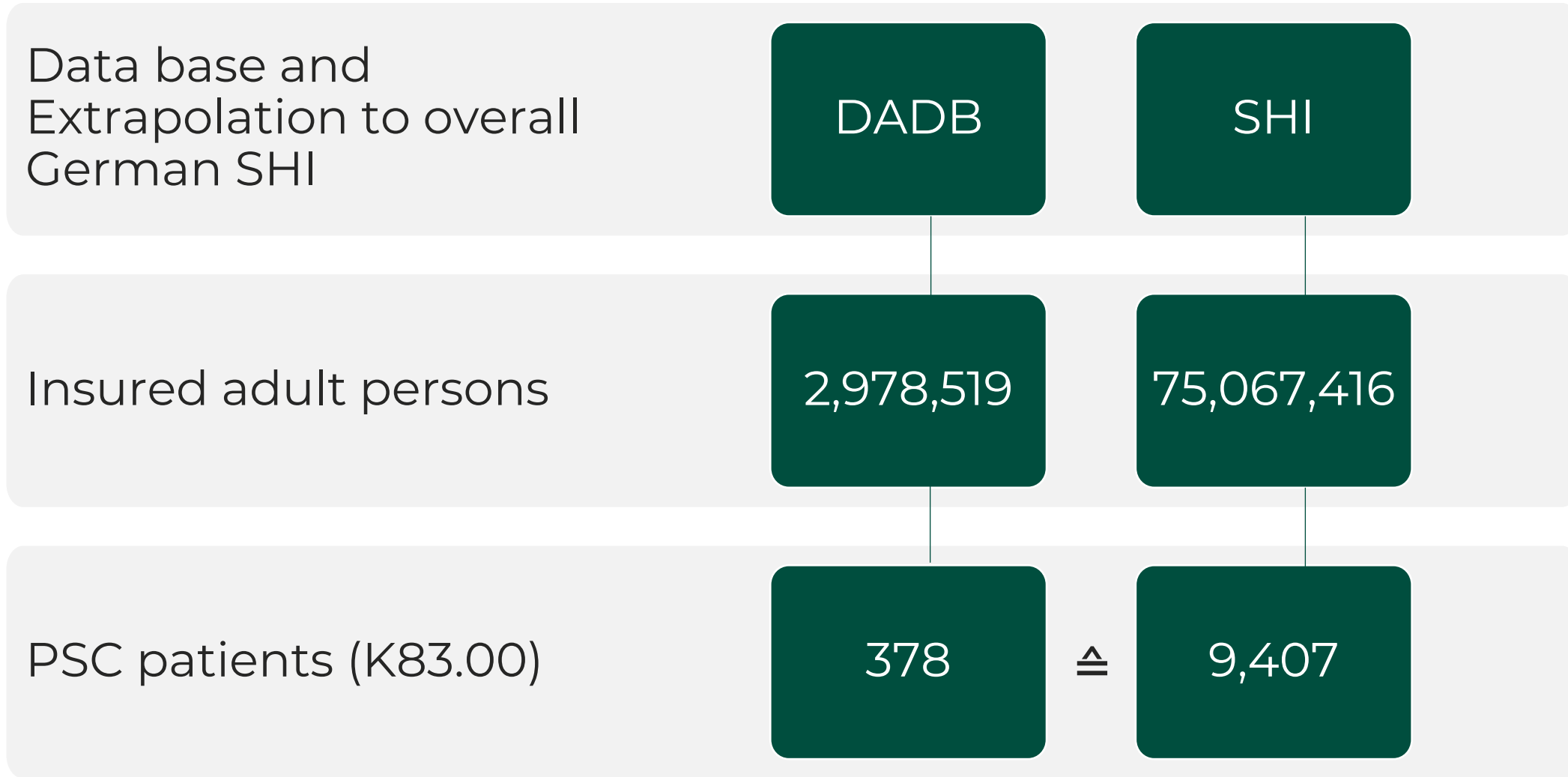


Fig. 1. Selection and extrapolation of PSC patients in 2022.

CONCLUSION

- The prevalence rate of PSC is 0.013% (95% CI: 0.011% – 0.014%).
- In comparison to the control group, PSC patients show a significantly higher risk of developing conditions such as liver fibrosis and carcinoma.
- The PSC patients' costs were around 17 times higher than in the control group.
- This study highlights the healthcare burden of PSC, including serious comorbidities and the prevalent use of off-label drugs, underscoring the urgency for optimized care strategies.

RESULTS

Prevalence and incidence:

- The study revealed a PSC prevalence (Fig. 2) of 13/100'000 (95% CI: 11 – 14) and an incidence rate of 2.7/100'000 (95% CI: 2.1 – 3.4).

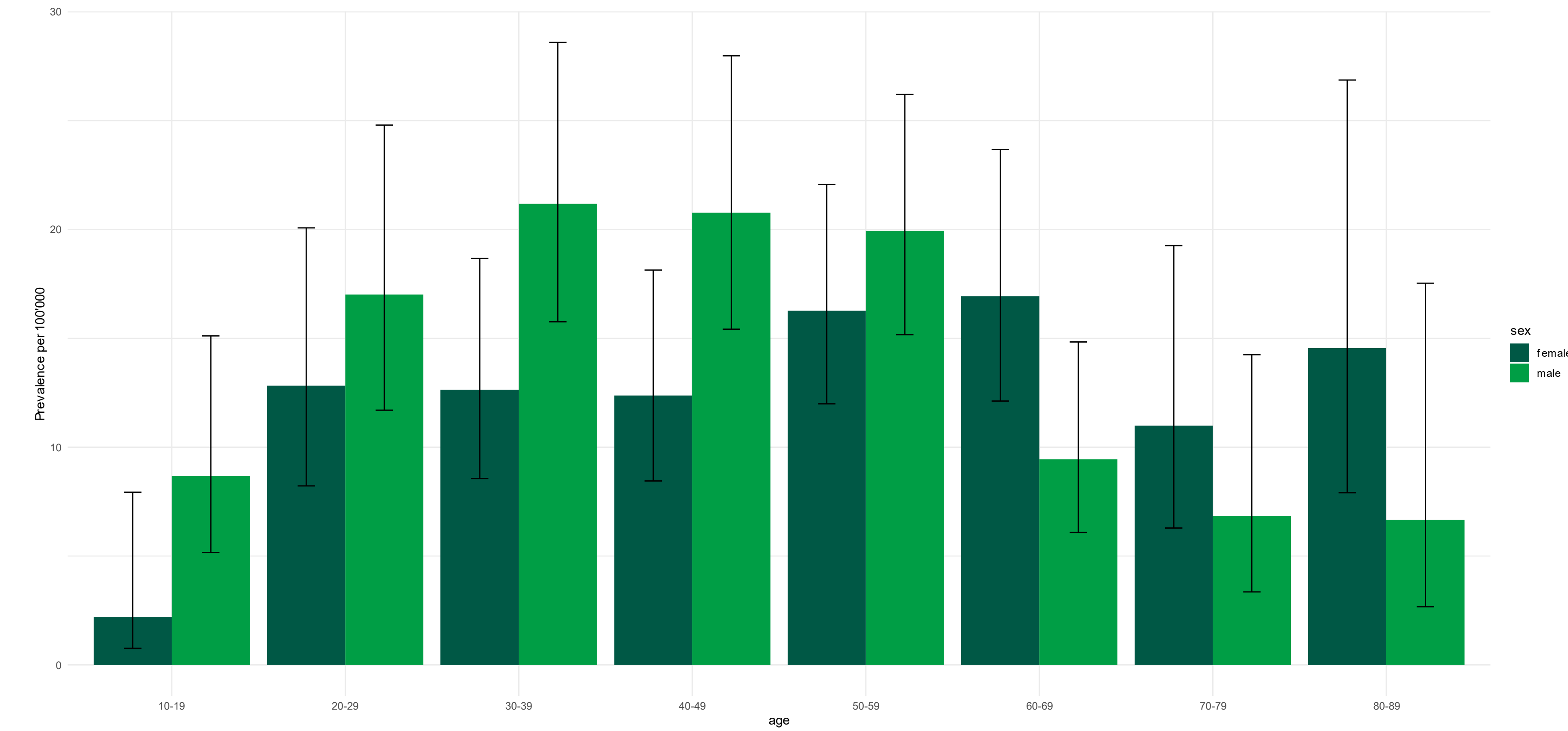


Fig. 2. Prevalence rate of PSC stratified by age group.

Comorbidities:

- When compared to the matched control group (Tab. 1), PSC patients exhibited a significantly higher risk of developing conditions such as inflammatory bowel disease (ulcerative colitis, Crohn's disease) and liver fibrosis as well as cholangiocarcinoma or hepatocellular carcinoma.
- Additionally, PSC patients constitute 15% of those receiving liver transplants.

Tab. 1. Comparison of PSC patients with matched control group and proportion per following category.

	PSC patients Patients/Proportion [95% CI]	Matched control group Persons/Proportion [95% CI]
Base population		
Base population	9,407	94,067
Symptoms		
Anxiety	7.99% [5.70%; 11.90%]	7.30% [6.51%; 8.21%]
Cholangitis	20.90% [17.25%; 25.42%]	0.02% [0.00%; 3.21%]
Depression	24.31% [20.35%; 28.93%]	18.45% [17.26%; 19.74%]
Fever	3.15% [1.85%; 8.97%]	2.40% [1.96%; 2.98%]
Weight loss	2.78% [1.50%; 7.87%]	0.88% [0.61%; 1.33%]
Hyperbilirubinaemia	3.78% [2.20%; 8.38%]	0.05% [0.01%; 1.72%]
Pruritus	4.91% [3.16%; 9.03%]	1.65% [1.28%; 2.20%]
Fatigue	10.84% [8.18%; 14.97%]	6.09% [5.36%; 6.94%]
Pain	21.87% [18.19%; 26.20%]	10.38% [9.43%; 11.42%]
Specific Comorbidities		
Crohn's disease	14.69% [11.63%; 19.14%]	0.49% [0.32%; 0.96%]
Fibrosis of liver	5.23% [3.52%; 9.31%]	0.05% [0.01%; 1.75%]
Cirrhosis of liver	13.45% [10.52%; 17.62%]	0.21% [0.11%; 0.75%]
Ulcerative colitis	40.12% [35.84%; 45.01%]	0.45% [0.28%; 0.94%]
Carcinoma		
Cholangiocarcinoma or hepatocellular carcinoma	5.28% [3.45%; 9.38%]	0.03% [0.00%; 0.31%]
Colon carcinoma	1.47% [0.69%; 8.18%]	0.33% [0.19%; 0.77%]
Liver transplantations		
Liver transplantations	0.75% [0.26%; 3.30%]	-

Treatment:

- In 2022, 15% (95% CI: 11.8% – 19.3%) of PSC patients underwent an ERCP.
- Due to the lack of approved therapies, 76% of the PSC patients were treated with off-label UDCA even though the evidence for the use of UDCA is controversial.

Sick leave:

- On average, PSC patients take 30 days of sick leave, compared to 19 days for individuals in the control group.

Costs:

- The average HCRU costs for PSC patients were €61,207 (95% CI: €44,472 – €83,324), markedly higher than the control group's average of €3,600 (95% CI: €3,291 – €3,915).

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