

A German claims database analysis of epidemiology, treatment patterns, and healthcare resource utilization of patients with primary biliary cholangitis (PBC)

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KEY LEARNINGS

- The proportion of prevalent patients with PBC who are untreated is quite high (20.4% on average).
- OCA (1.7% on average) and fibrates (2.8% on average) were used rarely.
- The majority of prevalent patients with PBC (60.4% on average) suffered from vascular and pulmonary comorbidities, most notably essential (primary) hypertension.

RATIONALE AND BACKGROUND

- PBC is a rare, chronic cholestatic liver disease occurring predominantly in females aged 40 years and older.
- If left untreated, the survival of patients with PBC is significantly lower than that of the general population.
- PBC is characterized by lymphocytic cholangitis and intralobular bile duct destruction leading to development of fibrosis, cirrhosis, and liver failure.
- Currently, diagnosis of PBC is typically made on the basis of elevated alkaline phosphatase (ALP) as well as bilirubin values and positive antimitochondrial antibody reactivity.
- Due to the rarity of the disease, there are limited real-world-evidence (RWE) data available from Germany.

STUDY AIM

- To examine the epidemiology of PBC and associated treatment landscape, HCRU, HCRU-related costs, and regional differences in patient profiles and experiences within the German SHI patient population.

CONCLUSIONS

- This study reveals detailed insights into the healthcare situation of PBC in Germany, including the current treatment situation, underscoring the urgent need for improved care strategies due to high rates of treatment discontinuation and missing treatment initiation.
- Furthermore, the recommended second line treatment with OCA or fibrates is rarely used.

METHODS

Study design

- This retrospective cohort study utilized German claims data from a representative sample of the Statutory Health Insurance (SHI), comprising 2.4 million adult, fully insured individuals from the 'German Analysis Database for Evaluation and Health Services Research' (DADB) [1].
- Where applicable, DADB counts were extrapolated to the SHI population, accounting for differences in age, sex, and regional distribution. Therefore, extrapolation factors were calculated for each AGG in each KV region based on data from the BMG and applied to DADB patient counts.

Study population

- Adult patients diagnosed with PBC from 2017–2022.
- Inclusion based on the M1Q criterion: at least one confirmed outpatient or main/secondary inpatient diagnosis per calendar year.

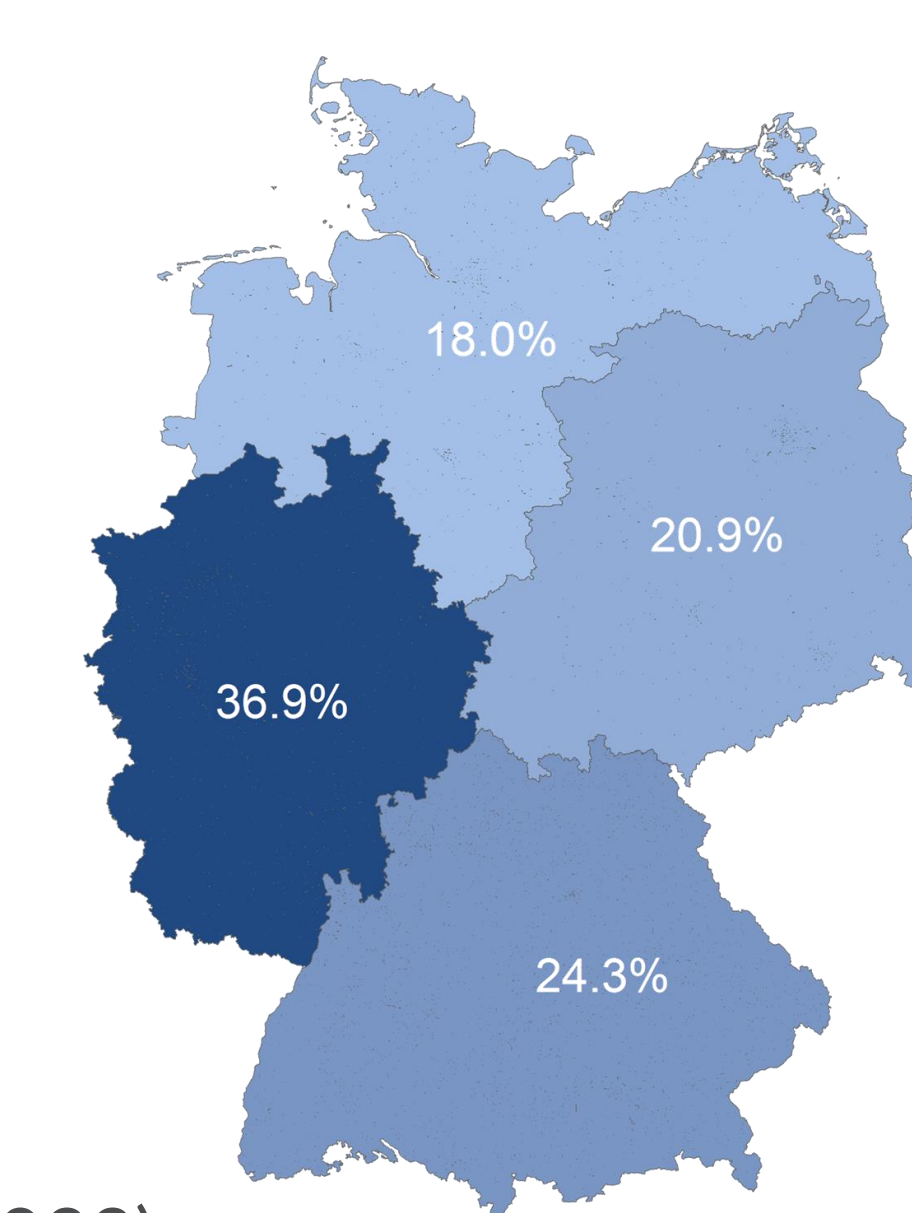
RESULTS

Based on annually calculated results, the average across the calendar years is provided.

Epidemiology

- An average of 1,192 patients with PBC were identified in the DADB, referring to 32,792 SHI patients in SHI and a prevalence of 5.3 per 10,000 insureds with considerable regional differences (Figure 1).
- The incidence rose from 0.78 per 10,000 insured individuals (2017) to 1.12 per 10,000 (2022), corresponding to 7,006 SHI patients with PBC (2022).

Figure 1. Prevalence 2022



Treatment

- From the prevalent patients with PBC, 79.4% received UDCA, 1.7% OCA, 2.8% fibrates, and 20.4% received none of these treatments in the calendar year of prevalence. Patients were considered in all identified treatment groups if they received more than one of these medications.
- 98.9% of therapy-naïve patients with PBC, who subsequently received treatment, initiated treatment with UDCA, typically 22 days (median) after their first PBC diagnosis (Figure 2).
- 47.1% of patients with PBC continued UDCA treatment over the whole assessed follow-up period of three years (Figure 2).
- 33.1% of the patients with PBC with therapy initiation discontinued UDCA as first line of therapy without any further therapy initiations within the three years of assessed follow-up (Figure 2).
- Considering all available treatment discontinuations, for UDCA, a median treatment duration of 325 days was observed and for fibrates 184 days.

Diagnosing and treating institutions and specialists

- 77.3% of incident patients with PBC received their initial PBC diagnosis in the outpatient setting, mainly by internists, gastroenterologists or general practitioners.
- Internists, gastroenterologists, general practitioners and hematologists as well as oncologists were mainly responsible for the prescription of UDCA, OCA and fibrates.

Comorbidities

- 60.4% of prevalent patients with PBC had vascular and pulmonary diseases, 58.7% endocrine and metabolic diseases, 26.9% autoimmune diseases, 23.3% mental illnesses and brain diseases, 19.8% musculoskeletal diseases and 5.4% gastrointestinal diseases. 11.6% showed none of the considered comorbidities.

HCRU and HCRU-related costs

- Management of PBC mainly occurred in the outpatient setting, and the median number of outpatient visits per year was 16, of which 4 were assigned to a confirmed PBC diagnosis (Figure 3).
- The majority of prevalent patients with PBC were not hospitalized.
- Among the hospitalized patients with PBC, the median hospitalization time was 8 days, increasing to 9 days when considering only hospitalizations assigned to a main or secondary PBC diagnosis. (Figure 3).
- The median incapacity to work was 21 days, with 8 of those days related to a confirmed PBC diagnosis.
- Furthermore, HCRU-related costs were determined (Figure 4) and stratified by comorbidity group (Figure 5).
- Overall median annual costs¹ per patient were approximately €3,344 and €216,390 in the year of a liver transplantation.

Figure 2. Treatment lines

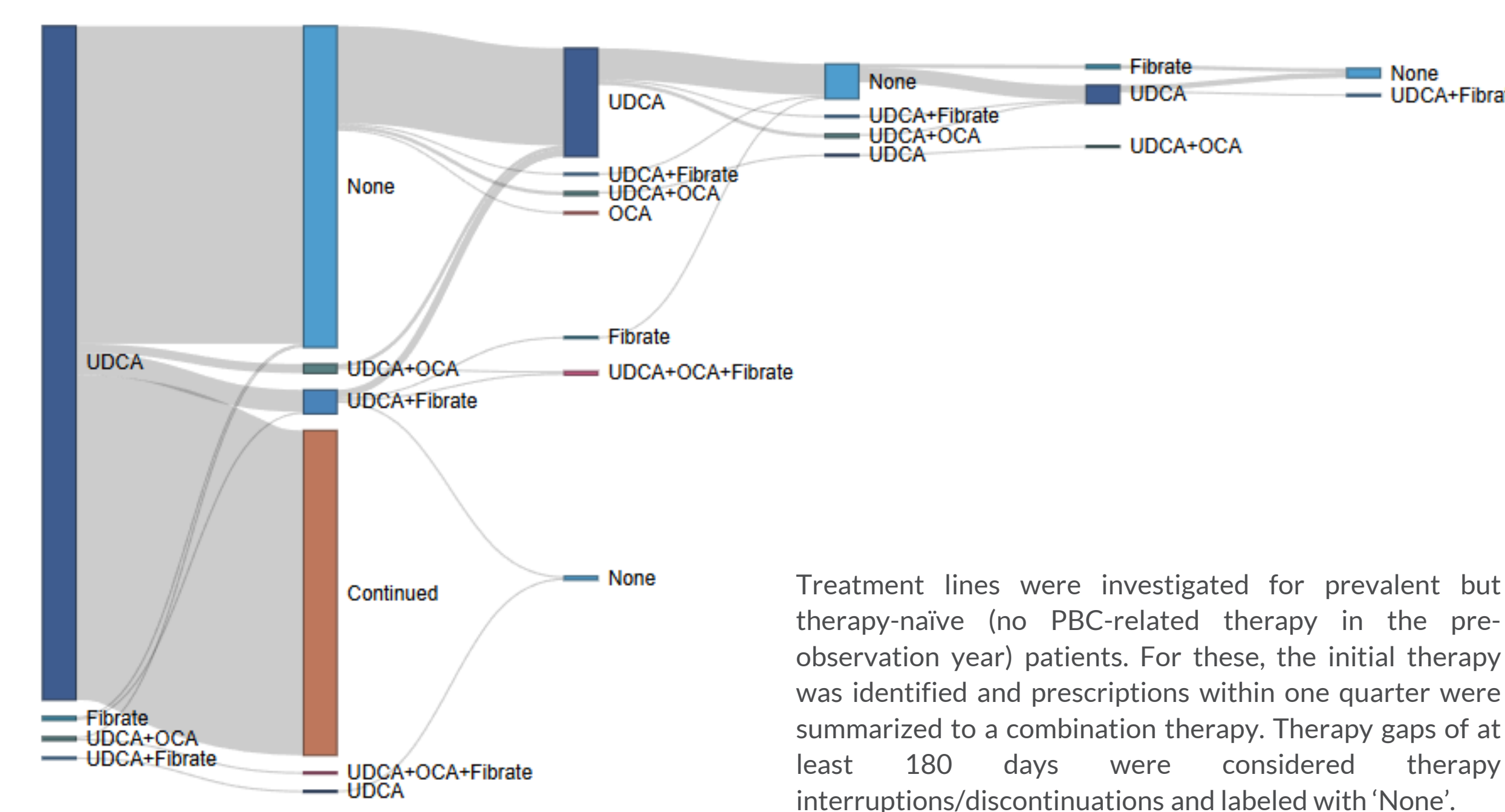
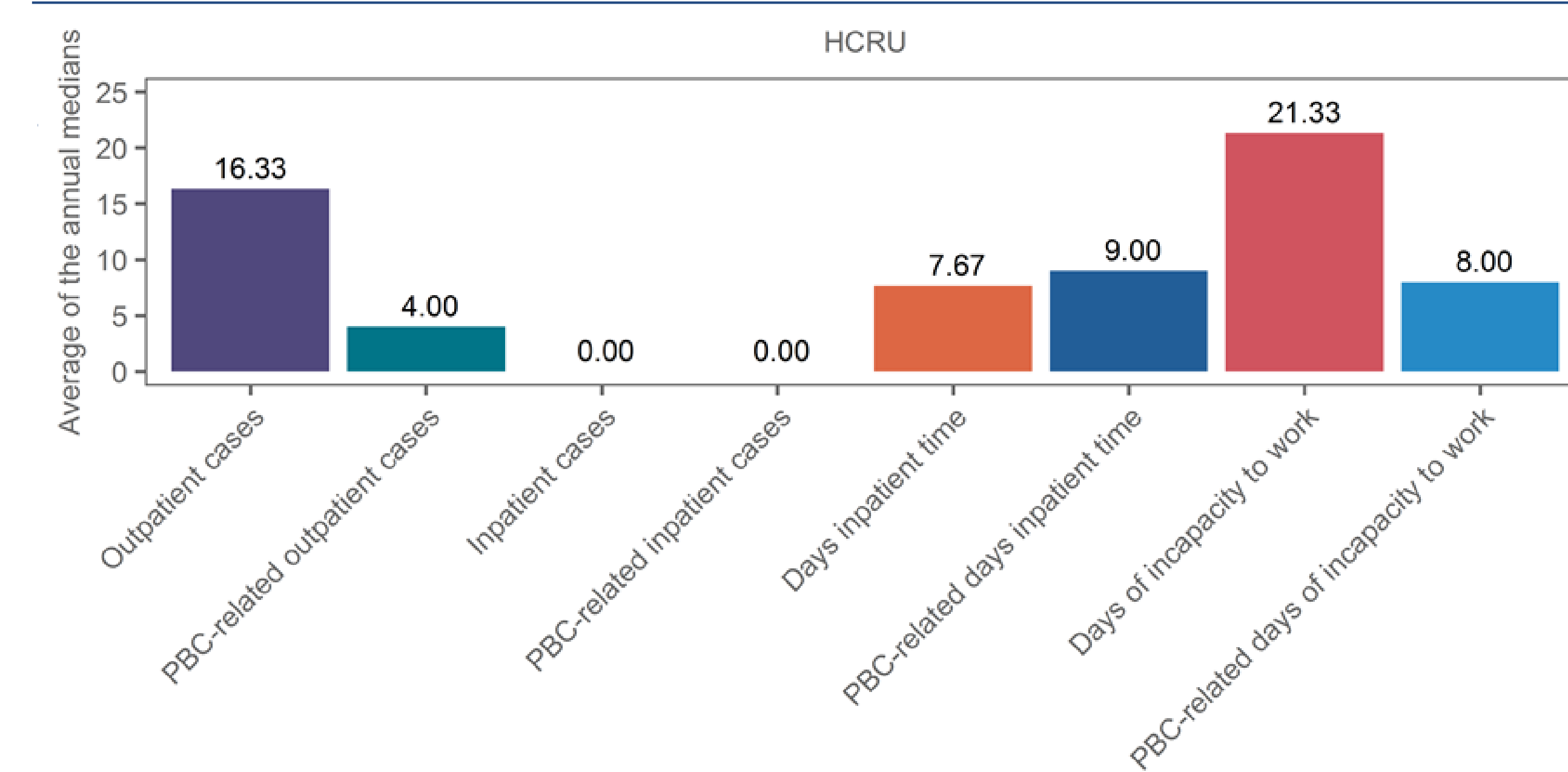
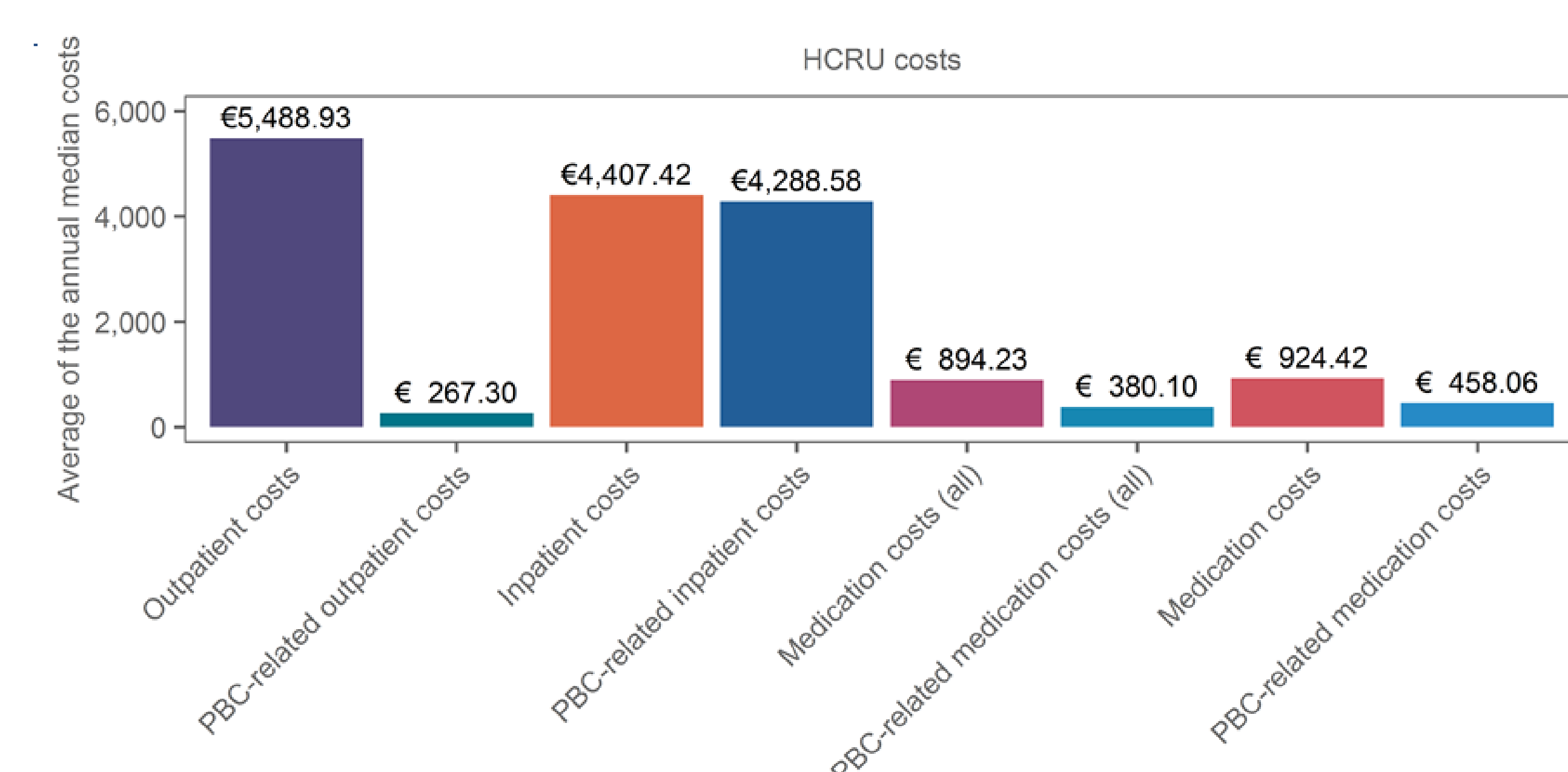


Figure 3. HCRU – average over years



Overall cases/time are independent of a PBC diagnosis, and for PBC-related values, only cases associated with a PBC diagnosis (according to the M1Q criterion) are included.

Figure 4. HCRU-related costs – average over years



Overall costs are independent of a PBC diagnosis, and for PBC-related costs, only cases associated with a PBC diagnosis (according to the M1Q criterion) are included.

Figure 5. HCRU-related costs – stratified by comorbidity group in 2022



Costs identified in 2022 were stratified by comorbidity group. Overall costs are independent of a PBC diagnosis, and for PBC-related costs, only cases associated with a PBC diagnosis (according to the M1Q criterion) are included.

Footnotes

1. Overall annual costs include outpatient costs, inpatient costs, dialysis costs, medication costs, dental costs, costs for remedy treatment, and sick pay costs.

References

1. German Analysis Database for Evaluation and Health Services Research (DADB)
<https://www.gesundheitsforen.net/services/gesundheitsoekonomie/deutsche-analysedatenbank>

Abbreviations

AGG Age and gender group
BMG: ger. Bundesministerium für Gesundheit
KV: ger. Kassenärztliche Vereinigung
OCA: Obeticholic acid
UDCA: Ursodeoxycholic acid

Author contributions

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: All Authors; Drafting of the publication, or reviewing it critically for

important intellectual content: All Authors; Final approval of the publication: All Authors

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