Poster #EPH29

Prevalence of Claims-Reported Pruritus in Patients With Primary Biliary Cholangitis Overall and Among Those Treated With Obeticholic Acid

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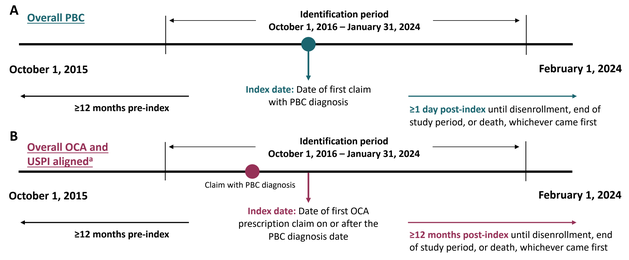
Introduction

- Pruritus is a common symptom of primary biliary cholangitis (PBC; ~80%-90% of patients) that impacts health-related quality of life[1,2]
  - A substantial proportion of patients with PBC (37%-53%) report clinically significant pruritus, as determined by a score of ≥7 on the PBC-40 itch domain[1,2]
- Obeticholic acid (OCA), a selective and potent farnesoid X receptor agonist, is approved as a second-line treatment for PBC in patients who have inadequate response or intolerance to ursodeoxycholic acid[3,4]
- Pruritus is a known adverse event of OCA, with clinical trial data reporting rates of 56-68%[3]
  - Among OCA-treated patients without baseline pruritus, 29%-42% reported treatment-emergent pruritus[5]
  - Rates of pruritus vary in real-world settings, with 27%-41% of patients reporting pruritus after OCA treatment and 21% reporting incident pruritus, per electronic health record data[6,7]
- The objective of this study was to assess the prevalence of claims-reported pruritus in patients with PBC, including a subset who initiated OCA treatment

Methods

- This analysis identified adults with PBC using Komodo's Healthcare Map (**Figure 1A**)
  - Komodo's Healthcare Map is a longitudinal claims database with claims data from >330 million patients in the US covered by commercial, Medicare, and Medicaid plans[8-10]
- Overall study inclusion criteria
  - Diagnosis of PBC (≥2 outpatient claims on different days or ≥1 inpatient claim)[11] between October 1, 2016, and January 31, 2024
  - ≥18 years of age on the index date (date of first claim with a PBC diagnosis)
- Among these patients, we identified a subset who initiated OCA, including a separate cohort with characteristics generally aligned to OCA 2021 US Prescribing Information (USPI) criteria
  - USPI criteria contraindicate the use of OCA in patients with PBC with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension[4]
  - Patients in the USPI-aligned cohort may have been enrolled prior to 2021
- For OCA-treated patients, the date of first OCA prescription claim on or after the PBC diagnosis date was set as the index date (**Figure 1B**)
- Patients were enrolled for ≥12 months pre-index and ≥1 day (overall PBC) or ≥12 months (OCA treated) post-index until disenrollment, end of the study period, or death, whichever came first
  - A sensitivity analysis was conducted among OCA-treated patients enrolled for ≥6 months post-index until disenrollment, end of the study period, or death, whichever came first

Figure 1. Study design for the **(A)** overall PBC cohort and **(B)** OCA-treated cohorts (overall OCA and USPI aligned)



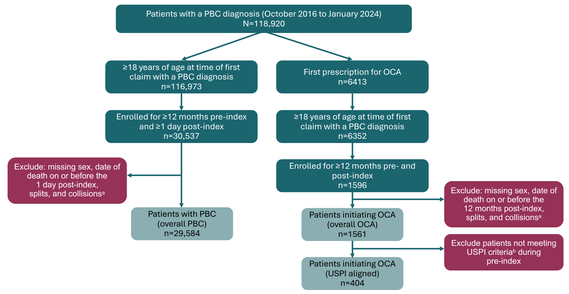
Abbreviations: OCA, obeticholic acid; PBC, primary biliary cholangitis; USPI, US Prescribing Information.
[a]USPI criteria contraindicate the use of OCA in patients with PBC with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.

- Descriptive analyses were used for patient characteristics and claims-reported pruritus prevalence
- Claims-reported pruritus was defined using *International Classification of Diseases, Tenth Revision, Clinical Modification* code L29.X
- The time to first claims-reported pruritus after OCA initiation was examined among patients with only post-index claims-reported pruritus (ie, incident claims-reported pruritus) in the 1-year period after OCA initiation for the overall OCA and USPI-aligned cohorts
  - The time from incident claims-reported pruritus diagnosis after the index date to OCA discontinuation was also assessed
  - Discontinuation was defined as a gap of ≥60 in days' supply of OCA

Results

- We identified 29,584 patients with PBC who met study inclusion criteria (**Figure 2**)
- Among patients who met study inclusion criteria, 1561 patients initiated OCA and 404 patients met USPI-aligned criteria since 2016 (**Figure 2**)

Figure 2. Attrition of overall patients with PBC and patients initiating OCA (overall and USPI aligned)



Abbreviations: OCA, obeticholic acid; PBC, primary biliary cholangitis; USPI, US Prescribing Information.
[a]Collisions represented deidentified patient records across health plans with the potential to represent the same individual and were excluded from the study.
[b]USPI criteria contraindicate the use of OCA in patients with PBC with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.

- The mean (SD) age of the overall population with PBC was 59 (13) years, and patients initiating OCA were slightly younger (mean [SD] age, 55 [11] years) (**Table 1**)
  - Patients with claims-reported pruritus were younger than the overall population within each cohort
- In all 3 cohorts, most patients were enrolled in commercial or Medicare insurance
- Sex, race/ethnicity, and baseline Charlson Comorbidity Index score of patients with claims-reported pruritus were similar to these characteristics among the overall population within each cohort

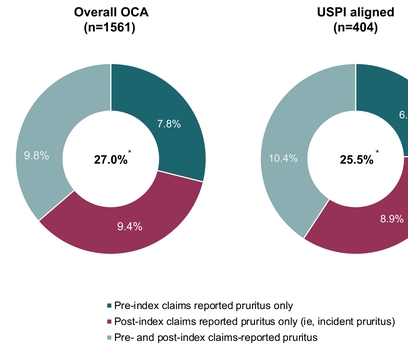
Table 1. Patient characteristics of the overall PBC cohort and OCA cohorts (overall and USPI aligned)

	Overall PBC		Overall OCA		USPI aligned	
	All patients n=29,584	With claims-reported pruritus n=6223	All patients n=1561	With claims-reported pruritus (pre- and/or post-index) n=422	All patients n=404	With claims-reported pruritus (pre- and/or post-index) n=103
Age, y						
Mean (SD)	58.5 (13.1)	56.6 (13.4)	54.9 (10.8)	52.0 (11.1)	54.8 (10.9)	52.5 (10.1)
Median (IQR)	59.0 (51.0, 67.0)	57.0 (48.0, 65.0)	55.0 (48.0, 62.0)	52.0 (45.3, 59.0)	54.5 (48.0, 61.0)	52.0 (45.0, 58.0)
Range	18.0-89.0	18.0-88.0	19.0-86.0	19.0-85.0	21.0-85.0	33.0-85.0
Sex, n (%)						
Female	24,119 (81.5)	5210 (83.7)	1434 (91.9)	394 (93.4)	373 (92.3)	99 (96.1)
Male	5465 (18.5)	1013 (16.3)	127 (8.1)	28 (6.6)	31 (7.7)	4 (3.9)
Race/ethnicity, n (%)						
White	15,201 (51.4)	3055 (49.1)	770 (49.3)	197 (46.7)	168 (41.6)	40 (38.8)
Black or African American	2313 (7.8)	612 (9.8)	93 (6.0)	35 (8.3)	25 (6.2)	6 (5.8)
Hispanic or Latino	5422 (18.3)	1237 (19.9)	326 (20.9)	99 (23.5)	124 (30.7)	34 (33.0)
Asian or Pacific Islander	1021 (3.5)	214 (3.4)	42 (2.7)	11 (2.6)	10 (2.5)	3 (2.9)
Other	1191 (4.0)	226 (3.6)	68 (4.4)	13 (3.1)	17 (4.2)	3 (2.9)
Unknown	4436 (15.0)	879 (14.1)	262 (16.8)	67 (15.9)	60 (14.9)	17 (16.5)
Insurance, n (%)						
Commercial	12,211 (41.3)	2513 (40.4)	762 (48.8)	183 (43.4)	202 (50.0)	48 (46.6)
Medicare	9219 (31.2)	1849 (29.7)	340 (21.8)	110 (26.1)	85 (21.0)	27 (26.2)
Medicaid	5511 (18.6)	1320 (21.2)	302 (19.3)	73 (17.3)	67 (16.6)	15 (14.6)
Other[a]	2643 (8.9)	541 (8.7)	157 (10.1)	56 (13.3)	50 (12.4)	13 (12.6)
Baseline CCI score						
Mean (SD)	3.1 (2.5)	3.2 (2.6)	2.4 (1.8)	2.6 (1.9)	2.3 (1.7)	2.6 (1.8)
Median (IQR)	2.0 (1.0, 4.0)	2.0 (1.0, 4.0)	2.0 (1.0, 3.0)	2.0 (1.0, 4.0)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)

Abbreviations: CCI, Charlson Comorbidity Index; IQR, interquartile range; OCA, obeticholic acid; PBC, primary biliary cholangitis; USPI, US Prescribing Information.
[a]"Other" insurance included exchange plans and plans with missing type.

- Claims-reported pruritus was observed in 21.0% of overall patients with PBC
- Before initiating OCA, claims-reported pruritus was observed in 17.6% (overall OCA) and 16.6% (USPI aligned) of patients
- Claims-reported pruritus before and after OCA initiation was observed in 9.8% (overall OCA) and 10.4% (USPI aligned) of patients (**Figure 3**)
- Incident claims-reported pruritus after OCA initiation was observed in 9.4% (overall OCA) and 8.9% (USPI aligned) of patients (**Figure 3**)

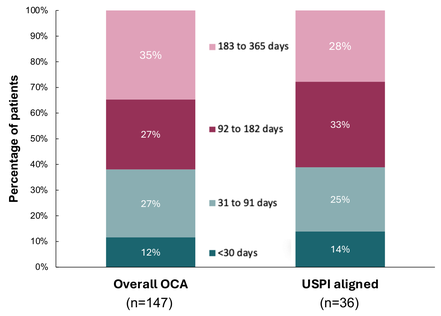
Figure 3. Prevalence of claims-reported pruritus in patients initiating OCA



Abbreviations: OCA, obeticholic acid; USPI, US Prescribing Information.
*Percentage of patients who had pre- and/or post-index claims-reported pruritus.

- In a sensitivity analysis of patients treated with OCA and enrolled for ≥6 months post-index, the results changed only slightly, even though sample size increased (n=1849 [overall OCA]; n=457 [USPI aligned])
  - Before initiating OCA, claims-reported pruritus was observed in 16.9% (overall OCA) and 16.6% (USPI aligned) of patients
  - Incident claims-reported pruritus after OCA initiation was observed in 6.7% (overall OCA) and 7.0% (USPI aligned) of patients
- Most OCA-treated patients had their first occurrence of claims-reported pruritus ≥92 days after treatment initiation (**Figure 4**)
  - Most patients (overall OCA, 65%; USPI aligned, 72%) with an incident pruritus claim had this claim within the first 6 months after OCA initiation

Figure 4. Time to first claims-reported pruritus after OCA initiation (overall OCA and USPI-aligned cohorts)



Abbreviations: OCA, obeticholic acid; USPI, US Prescribing Information.

- The median (95% CI) time to OCA discontinuation after incident claims-reported pruritus was approximately 1 year (overall OCA, 369 [245-581] days; USPI aligned, 341 [177-not estimable] days)

Study Limitations

- Komodo's Healthcare Map includes complete medical and pharmacy claims data from health insurers but does not include individuals without insurance
- Patients may have been treated for pruritus, but it may not have been documented as a diagnosis code, resulting in possible underreporting of pruritus[2]
  - Further, not all patients may have reported their pruritus
- Patient follow-up time varied and was not adjusted in the analyses

Conclusions

- Although pruritus is underreported in claims (21% of patients in this analysis vs ~80%-90% via self-reporting),[1,2] these data potentially reflect relevant pruritus-related medical visits and may be important to payers and health systems
- Prevalence estimates of claims-reported pruritus in the overall PBC and OCA cohorts were similar
- Rates of incident claims-reported pruritus after OCA initiation were lower than rates in real-world[6,7] and clinical trial[5] settings
- The majority of incident claims-reported pruritus was observed within the first 6 months after OCA initiation, which aligns with data from the phase 3 POISE study[3]

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Author Disclosures

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