Characterizing patients with pruritus and primary biliary cholangitis (PBC) in the PicnicHealth PBC cohort; contrasting medical record-documented pruritus with patient-reported pruritus from the PBC-40

Poster No. 4748

Usha Gungabissoon[1], Helen T Smith[1], Robyn von Maltzahn[1], John Logie[1], Jolyon Fairburn-Beech[1], Liyuan Ma[2], Sivangi Nair[3], Dhirishiya P[3], Ashleigh McGirr[4]*, Haley S Friedler[5], Meghan Tierney[5], Christopher Rowe[5]

[1]GSK, London, UK; [2]GSK, Collegeville, PA, USA; [3]GSK, Bangalore, India; [4]GSK, Mississauga, ON, Canada; [5]PicnicHealth, San Francisco, CA, USA
*Presenting author

Background

Cholestatic pruritus (itch) is a common symptom in patients with primary biliary cholangitis (PBC), affecting up to 74% of patients over the course of this rare disease.[1]

Pruritus can be debilitating and is associated with a negative impact on physical and emotional well-being.[2-4] Severe pruritus limits daily life activities and is associated with fatigue, depression, and even suicidal ideation.

Previous analyses of administrative healthcare databases, used routinely by medical providers in the USA to record clinical and laboratory data, have indicated that pruritus in patients with PBC may be under-recorded.[5] Possible reasons for this may include:

i. Only patients with severe pruritus interact with physicians and have pruritus recorded in their medical history;
ii. Non-specific coding is used to record PBC symptoms as no International Classification of Diseases (ICD) code exists for cholestatic pruritus;
iii. Physicians manage pruritus but do not record a pruritus diagnosis;
iv. The off-label use of medications to manage pruritus (that are licensed for non-pruritus indications) makes it difficult to reliably describe specific pruritus management;
v. The paucity of approved treatments for cholestatic pruritus means the symptom is less explored by physicians.

To overcome these limitations and understand the severity and prevalence of pruritus, PicnicHealth has compiled a real-world, de-identified, patient-level database derived from the medical records of patients with PBC.

The dataset is augmented with a patient-reported outcome (PRO) measure, the PBC-40, which captures a range of HRQoL impacts, including the severity of itch.

Aims

To report characteristics of patients with PBC who have pruritus recorded in their medical record and the degree of overlap with pruritus reported via the PBC-40.

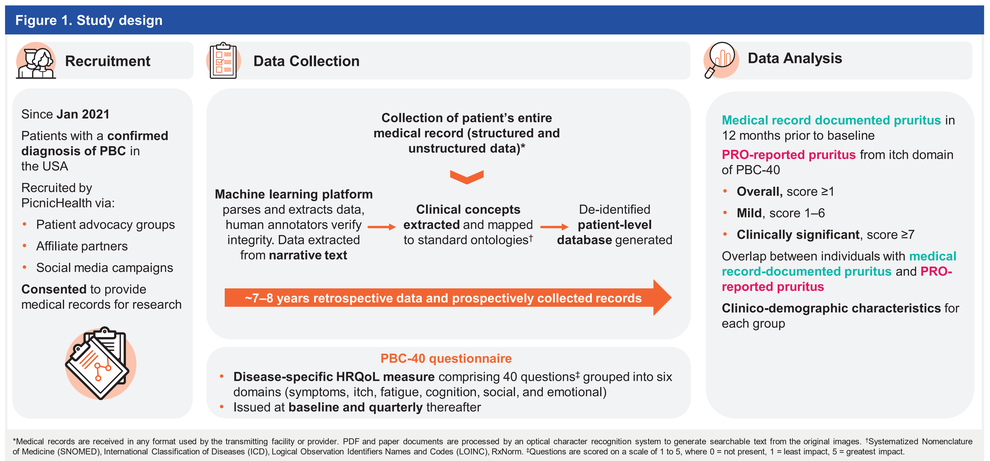
Methods

Study design is summarized in **Figure 1**.

The analysis population included all participants who had completed the PBC-40 itch domain at baseline (defined as enrolment into the cohort).

Clinico-demographic characteristics were summarized with descriptive statistics.

Figure 1. Study design



*Medical records are received in any format used by the transmitting facility or provider. PDF and paper documents are processed by an optical character recognition system to generate searchable text from the original images. †Systematized Nomenclature of Medicine (SNOMED), International Classification of Diseases (ICD), Logical Observation Identifiers Names and Codes (LOINC), RxNorm. ‡Questions are scored on a scale of 1 to 5, where 0 = not present, 1 = least impact, 5 = greatest impact.

Results

As of May 2022, 225 patients were recruited and included in the analysis.

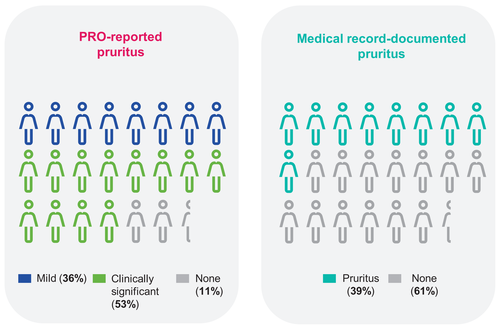
Patient demographics in the overall population were broadly consistent with the known clinico-demographic profile of patients with PBC and are presented at this meeting, **Poster 4775**.

Prevalence of pruritus

Overall, 89% of patients (n=200) had **PRO-reported (PR) pruritus** of any severity at baseline; 36% (n=80) had mild pruritus, 53% (n=120) had clinically significant pruritus (**Figure 2**).

In the 12 months prior to baseline, 39% of patients (n=88) had **medical record-documented (MRD) pruritus** (**Figure 2**). Of the 137 patients with no recent pruritus in their medical record, 88% (n=121) of them had a doctor visit during the 12 months prior to baseline.

Figure 2. Proportion of patients with PR and MRD* pruritus at baseline



Overall N=225. Each icon represents 10 patients. Mild, defined as PBC-40 itch domain score 1–6; clinically significant as score ≥7. *Recorded within the 12-month period prior to baseline on patient medical record.

Clinico-demographic characteristics of patients with MRD or PR pruritus

Demographic features, clinical characteristics, and use of treatments for PBC are shown in **Table 1**.

Mean baseline alkaline phosphatase (ALP) was higher for those with **MRD pruritus** and clinically significant **PR pruritus** than those with mild or no **PR pruritus**. Patients with clinically significant itch also tended to be younger at PBC diagnosis and baseline.

A subset of patients had PBC staging data available. Patients with mild **PR pruritus** were more likely to have Stage 1/2 PBC, while patients with clinically significant itch on the PBC-40 had the highest prevalence of Stage 4 disease.

Overlap between PR and MRD pruritus

The proportion of patients with no, mild or severe **PR pruritus** according to whether they had **MRD pruritus** is shown in **Figure 3.**

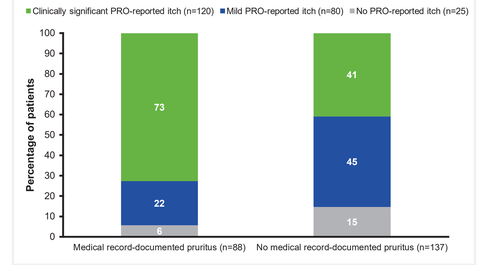
- Of the 137 patients without **MRD pruritus**, 85% (n=117) had **PR itch**, including 41% (n=56) who had clinically significant pruritus.

Table 1. Clinico-demographic characteristics and use of PBC treatments for patients with MRD pruritus and those with or without PBC-40 PR pruritus*

	No PR pruritus (n=25)	Mild PR pruritus (n=80)	Clinically significant PR pruritus (n=120)	Overall PR pruritus (n=200)	MRD pruritus¶ (n=88)
Demographics					
Sex Female, n (%)	24 (96)	78 (98)	118 (98)	196 (98)	86 (98)
Age at enrollment, y, mean (SD)	60.9 (10.6)	57.4 (11.6)	52.9 (9.7)	54.7 (10.7)	53.8 (11.3)
Age at PBC diagnosis, y, mean (SD)	54.7 (10.2)	52.2 (10.9)	48.1 (9.5)	49.8 (10.3)	48.4 (10.5)
PBC duration at baseline†, y, mean (SD)	6.2 (4.7)	5.3 (6.6)	4.8 (4.8)	5 (5.6)	5.3 (5.6)
Clinical characteristics					
PBC stage‡, n (%)	n=10	n=26	n=46	n=72	n=37
Stage 1	3 (30)	12 (46)	15 (33)	27 (38)	13 (35)
Stage 2	3 (30)	9 (35)	13 (28)	22 (31)	10 (27)
Stage 3	3 (30)	5 (19)	7 (15)	12 (17)	7 (19)
Stage 4	1 (10)	0 (0)	11 (24)	11 (15)	7 (19)
Cirrhosis, n (%)	8 (32)	20 (25)	38 (32)	58 (29)	31 (35)
ALP at baseline§, mean (SD), IU/L	157.2 (129.5)	158.6 (93.9)	212.5 (162.1)	192.0 (142.2)	221.9 (175.5)
PBC treatment					
Recent¶ use of UDCA, n (%)	22 (88)	69 (86)	105 (88)	174 (87)	83 (94)
Recent¶ use of obeticholic acid, n (%)	3 (12)	7 (9)	27 (23)	34 (17)	19 (22)
Recent¶ use of fibrates, n (%)	2 (8)	2 (3)	13 (11)	15 (8)	11 (13)

*Overall pruritus, defined as PBC-40 itch domain score ≥1; mild, defined as score 1–6; clinically significant, defined as score ≥7. No PR pruritus defined as an itch domain score 0. †Time since first recorded PBC diagnosis to baseline was used as a proxy for PBC duration. ‡Where available, extracted directly from medical records. Percentages calculated as proportion of patients with staging data available. §Closest to baseline but within 12 months. ¶Recorded within the 12-month period prior to baseline on patient medical record.
SD, standard deviation.

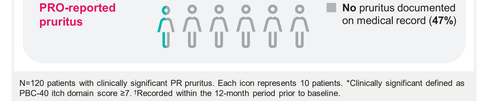
Figure 3. Proportion of patients with and without MRD pruritus* according to PR pruritus category†



*Recorded within the 12-month period prior to baseline on patient medical record. †Mild pruritus, defined as PBC-40 itch domain score 1–6; clinically significant, defined as score ≥7. No PR pruritus defined as an itch domain score 0. Numbers on bars represent percentage of patients in each group.

Of the 120 patients with clinically significant **PR pruritus**, 47% (n=56) had no mention of itch in their medical record (**Figure 4**).

Figure 4. Proportion of patients with clinically significant* PR pruritus who had pruritus documented on their medical record†



N=120 patients with clinically significant PR pruritus. Each icon represents 10 patients. *Clinically significant defined as PBC-40 itch domain score ≥7. †Recorded within the 12-month period prior to baseline.

Conclusions

In this study, patients with **MRD pruritus** were more likely to report clinically significant **PR pruritus**.

Patients with clinically significant **PR pruritus** tended to have higher ALP levels and a greater prevalence of Stage 4 disease than those patients reporting mild itch. Similarly, those with **MRD itch** had higher ALP levels.

However, almost half of patients with clinically significant **PR pruritus** did not have itch recorded in their medical record, suggesting pruritus is under-reported.

This could reflect poor recording of pruritus diagnoses, the absence of specific coding for cholestatic pruritus, or a lack of discussion between patient and physician about itch - a situation made more likely due to the lack of approved, effective treatment options.

Disclosures

UG, HTS, RvM, JL, JF-B, LM, SN, DP, and **AM** are employees of, and hold shares in GSK. **HSF, MT,** and **CR** are employees of, and hold stock options in PicnicHealth. Study conduct and data analysis were performed by PicnicHealth funded by GSK. No funding was provided to PicnicHealth for poster development. Ashleigh McGirr was added as a poster author and contributed to poster development, but was not included on the original abstract. All authors were informed of, and agreed to, her inclusion as a poster author.

Acknowledgments

This study was funded by GSK (Study 218574). Medical writing support (in the form of writing poster content, including development of the initial draft based on author direction, incorporating author comments, developing figures, layout assistance, and grammatical editing) was provided by Gemma Corr, DPhil of Fishawack Indicia Ltd, UK, part of Fishawack Health, and was funded by GSK.

References

1. Hegade VS, et al. *Clin Gastroenterol Hepatol* 2019;17:1379–87.
2. Jin XY, Khan TM. *J Formos Med Assoc* 2016;115:689–702.
3. Mayo MJ, et al. *Dig Dis Sci* 2022; https://doi-org.gsk.idm.oclc.org/10.1007/s10620-022-07581-x.
4. Younossi ZM, et al. *Am J Gastroenterol* 2000;95:497–502.
5. Gungabissoon U, et al. *BMJ Open Gastroenterol* 2022;9:e000857.

Please scan the QR code to access the poster.

Please scan the QR code to access the related **Poster 4775** presented at this meeting.

Author email address: ashleigh.a.mcgirr@gsk.com

Presented at the American Association for the Study of Liver Disease (AASLD) The Liver Meeting, Washington DC, USA, November 4–8, 2022