Administrative Claims-Based Algorithm to Identify Patients with Primary Sclerosing Cholangitis

EPH84

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Introduction

- The diagnostic criteria for primary sclerosing cholangitis (PSC) are not well established. This is attributed to the lack of a specific International Classification of Diseases (ICD) diagnosis code for PSC prior to Oct 1, 2018, or availability of algorithms to identify patients with PSC
- The lack of a specific diagnosis code for PSC prior to this date has limited the use of real-world data to generate real-world evidence for patients with PSC
- The diagnosis code specific to PSC (K83.01) was approved by the Centers for Disease Control and Prevention in April 2018 and came into effect on Oct 1, 2018, thus possibly enabling the true diagnosis of PSC[1–3]
- Unfortunately, the relatively short time span since reporting of PSC using a specific diagnosis code might result in fewer patients diagnosed with this disease and continues to remain as a barrier to generate real-world evidence in PSC
- To address this gap, it is imperative to identify patients with high likelihood of receiving PSC diagnoses prior to implementation of the specific PSC diagnosis code on Oct 1, 2018 by developing an administrative claims-based algorithm

Objective

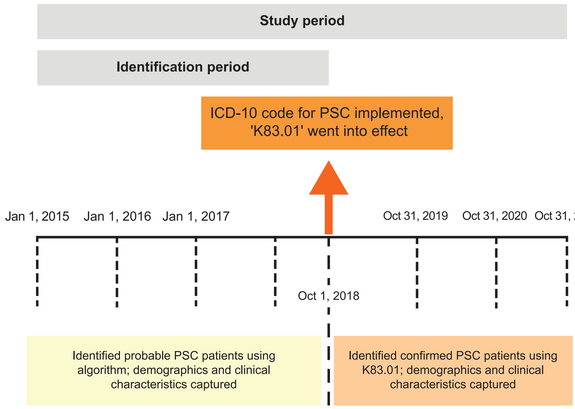
- This study aimed to develop an administrative claims-based algorithm to identify patients with PSC using a large claims database

Method

Study design and analysis

- Patients were identified who had made claims between Jan 1, 2015 and Sep 30, 2018 using the All Payer Claims Database, composed of open data source pharmacy and medical claims of insured patients in the US healthcare system (**Figure 1**)

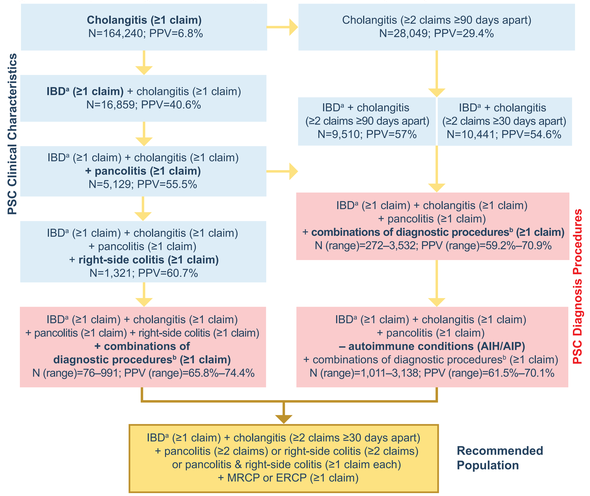
Figure 1. Study design



ICD-10, International Classification of Disease 10th Revision; PSC, primary sclerosing cholangitis.

- A stepwise algorithm was developed using combinations of medical claims for cholangitis and inflammatory bowel disease (IBD) along with IBD-related manifestations (pancolitis/right-sided colitis) and diagnostic procedures. Various exploratory analyses are highlighted in **Figure 2**
- Positive predictive values (PPVs) were estimated for patients with different combinations, using patients diagnosed with K83.01 after Oct 1, 2018 as confirmed PSC patients

Figure 2. Stepwise algorithm outlining various exploratory analyses



[a]IBD includes CD and UC. [b]Diagnostic pocedures include MRCP, ERCP, MRI, and PTC.
AIH, autoimmune hepatitis; AIP, autoimmune pancreatitis; CD, Crohn's disease; ERCP, endoscopic retrograde cholangiopancreatography; IBD, inflammatory bowel disease; MRCP, magnetic resonance cholangiopancreatography; MRI, magnetic resonance imaging; PPV, positive predictive value; PTC, percutaneous transhepatic cholangiography; UC, ulcerative colitis.

- Patient demographics and clinical characteristics were compared between algorithm-identified PSC patients and confirmed PSC patients (**Table 1**)
  - Chi-squared or Fisher's exact tests were used for categorical variables; t-tests were used for continuous variables that are normally distributed; nonparametric tests (e.g., the Wilcoxon signed-rank test) were used for continuous data that are not normally distributed
  - *p* values ≤0.05 were considered statistically significant. All analyses were conducted using R

Table 1. Key variables for comparing algorithm-identified and confirmed PSC patients

Patient characteristics	Clinical characteristics
• Age — categorized as ≤18, 19–44, 45–64, and 65+ groups • Sex — male and female • Race — Black or African American, White, Asian, Hawaiian, and Other/Unknown • Insurance type — Commercial, Medicare, Medicaid, Other/Unknown, None	• Quan-Charlson comorbidity score — categorized as 0, 1–2, 3–4, and ≥5 groups • Individual comorbid conditions: – Colorectal cancer – Bile duct stricture – Gall stones – Liver failure – Portal hypertension – Cholangiocarcinoma – Autoimmune hepatitis

PSC, primary sclerosing cholangitis.

Results

- The final recommended algorithm included:
  - patients with ≥1 claim of IBD + ≥2 claims of cholangitis (≥30 days apart) + ≥2 claims of pancolitis or ≥2 claims of right-sided colitis or ≥1 claim each of pancolitis and right-side colitis + ≥1 claim of magnetic resonance cholangiopancreatography (MRCP) or endoscopic retrograde cholangiopancreatography (ERCP)
- Algorithm-identified PSC patients (n=1,697), had a PPV of 74.3% (**Table 2**, shown by the red box)
- No significant differences were observed in patient demographics (except age) (**Table 3**) and clinical characteristics (**Table 4**) between algorithm-identified PSC patients (patients with a probable diagnosis of PSC) versus confirmed PSC patients (patients with an ICD-10 diagnosis code of K83.01)

Table 2. Algorithm-identified patients with PSC

Parameters	Number of patients						
IBD: ≥1 medical claim with CD or UC (in any position on the claim) from Jan 1, 2015 to Sep 30, 2018	307,725						
Cholangitis: ≥1 medical claim with cholangitis (in any position on the claim) from Jan 1, 2015 to Sep 30, 2018	16,859						
Cholangitis: ≥2 medical claims with cholangitis (in any position on the claim) from Jan 1, 2015 to Sep 30, 2018	13,321						
• Any 2 cholangitis claims (as above) separated by 30 days	10,441						
Pancolitis ± right-sided colitis: ≥2 medical claims with pancolitis OR ≥2 medical claims of right-sided colitis OR ≥1 medical claim pancolitis and ≥1 medical claim right-sided colitis (in any position on the claim) from Jan 1, 2015 to Sep 30, 2018	3,728						
Diagnostic procedures	No a–d	a only	b only	c only	a or b	a, b, c, or d	a, b, or c
a) MRCP	-	935	-	-	1,697	2,754	1,748
b) ERCP	-	-	1,193	-			
c) PTC	-	-	-	230	-		
d) MRI abdomen	-	-	-	-	-		-
PSC: ≥1 medical claim for PSC (K83.01) in any position on the medical claim after Oct 1, 2018	2,428	731	866	151	1,261	1,952	1,292
PPV	65.1%	78.2%	72.6%	65.7%	74.3%	70.9%	73.9%

CD, Crohn's disease; ERCP, endoscopic retrograde cholangiopancreatography; IBD, inflammatory bowel disease; MRCP, magnetic resonance cholangiopancreatography; MRI, magnetic resonance imaging; PPV, positive predictive value; PSC, primary sclerosing cholangitis; PTC, percutaneous transhepatic cholangiography.

Table 3. Comparing algorithm-identified PSC patients against confirmed PSC patients – patient demographics

Patient demographics	Algorithm-identified PSC patients, n=1,697	Confirmed PSC patients, n=1,261	*p* value
Sex, n (%)			0.5
Male	1,116 (65.8)	842 (66.8)	-
Female	581 (34.2)	419 (33.2)	-
Mean (SD) age at time of diagnosis, years	46 (18)	44 (18)	0.2
Age category, n (%)			0.016
≤18	87 (5.1)	77 (6.1)	-
19–44	741 (43.7)	583 (46.2)	-
45–64	550 (32.4)	419 (33.2)	-
≥65	317 (18.7)	182 (14.4)	-
Race, n (%)			0.7
Black or African American	44 (2.6)	34 (2.7)	-
White	433 (25.2)	348 (27.6)	-
Other/Unknown	1,180 (69.5)	849 (67.3)	-
Asian	7 (0.4)	5 (0.4)	-
Hawaiian	33 (1.9)	25 (2.0)	-
Insurance status, n (%)			0.7
Commercial	1,052 (62.0)	783 (62.1)	-
Medicaid	62 (3.7)	44 (3.5)	-
Medicare	106 (6.3)	66 (5.2)	-
None	448 (26.4)	348 (27.6)	-
Other/Unknown	29 (1.7)	20 (1.6)	-

PSC, primary sclerosing cholangitis; SD, standard deviation.

Table 4. Comparing algorithm-identified PSC patients against confirmed PSC patients – clinical characteristics

Patient demographics	Algorithm-identified PSC patients, n=1,697	Confirmed PSC patients, n=1,261	*p* value
Quan-Charlson comorbidity score, n (%)			0.4
0	170 (10.0)	114 (9.0)	-
1–2	445 (26.2)	364 (28.9)	-
3–4	266 (15.7)	195 (15.5)	-
≥5	816 (48.1)	588 (46.6)	-
Comorbidities, n (%)			
Colorectal cancer	21 (1.2)	14 (1.1)	0.8
Bile duct stricture	175 (10.3)	117 (9.3)	0.3
Gallstones	172 (10.1)	108 (8.6)	0.1
Liver failure	41 (2.4)	33 (2.6)	0.8
Portal hypertension	44 (2.6)	29 (2.3)	0.6
Cholangiocarcinoma	33 (1.9)	13 (1.0)	0.06
Autoimmune hepatitis	85 (5.0)	64 (5.1)	1

PSC, primary sclerosing cholangitis; SD, standard deviation.

Limitations

- Because 'presence of IBD' was one of the parameters in the identification algorithm, it does not include or represent the non-IBD PSC patient population
- True positives in this study defined using the ICD-10 code for PSC may not be truly positive − further validation in medical charts could add more value
- Sensitivity, specificity, and negative predictive values were not calculated

Conclusions

- **In administrative claims data, patients with the following algorithm had a PPV of 74.3% with a sample size of 1,697 patients with a probable diagnosis of PSC:**
  - **at least 1 claim for IBD +**
  - **at least 2 claims for cholangitis separated by at least 30 days apart +**
  - **at least 2 claims for pancolitis or at least 2 claims for right-sided colitis or 1 claim for pancolitis and 1 claim for right-sided colitis +**
  - **at least one procedural code for MRCP or ERCP**
- **The algorithm provides a solution to identify patients that are highly likely to have been diagnosed with PSC before the implementation of the PSC-specific code**
- **This addresses a critical gap in PSC patients' identification, thus subsequently contributing to generating real-world evidence for this rare disease condition**

References

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