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The Chronic Pancreatitis ICD-9-CM Code 577.1 is Inaccurate Compared to Gold-standard Clinical Diagnostic Scoring Systems

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Abstract

Objectives—Epidemiological studies employing administrative databases use the ICD-9-CM code (577.1) to identify patients with chronic pancreatitis (CP). We hypothesized that coding of CP in these databases is inaccurate.

Methods—We retrospectively reviewed the records of 1,343 consecutive patients having an ICD-9-CM code 577.1 between 10/01/05–11/01/08. We labeled patients as definite-CP or Non-CP, defined as fulfilling any of three diagnostic criteria for definite CP: Mayo, Ammann's and Japanese Pancreas Society (JPS) criteria.

Results—658 (49%) subjects had definite-CP. Definite CP among Mayo, Ammann's and JPS criteria was similar (49.0, 42.1 and 43.8, respectively). 84.3% of the definite CP fulfilled all three criteria, 6.7% fulfilled two and 9.0% filled one. Etiologies of definite-CP were definite/suspected non-alcohol (57.8%) or alcohol (33.5%), and not reported (8.7%). In Non-CP (n=685), 93.7% had available imaging (5.7% had EUS 5 or Cambridge II-III scores) and 63.5% had symptoms suggestive of CP but did not fulfill other features for definite-CP. CP vs Non-CP groups had similar mean ages but significantly more men and ever-smoking and ever-drinking alcohol.

Conclusion—51% of subjects coded as CP do not fulfill diagnostic criteria for definite-CP. Relying solely on the ICD-CM code for CP in administrative databases may lead to erroneous epidemiological conclusions.

Keywords

chronic pancreatitis; ICD-9-CM code 577.1; acute pancreatitis; epidemiology

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INTRODUCTION

Chronic pancreatitis (CP) arises from a progressive and irreversible inflammatory and fibrotic degenerative process associated with abnormal parenchymal and ductal imaging features and numerous clinical features including chronic abdominal pain, malabsorption, malnutrition and diabetes mellitus.¹ Diagnosis of CP is based on clinical criteria and remains challenging, particularly for “early disease”, when abdominal pain may be the sole manifestation. Aside from tissue diagnosis there is no universally accepted gold standard for diagnosis of CP, which contributes to observer (clinician or researcher) dependent subjectivity. To address this limitation, landmark efforts (1946–1984) aimed at classifying CP^{2–9} and led to development of clinical criteria for establishing a definite diagnosis of CP,^{10–13} for staging severity (Chari and Singer,¹⁴ ABC,¹⁵ Manchester,¹⁶) and classifying etiology.^{13, 14, 17}

Patients with a diagnosis of CP (and other conditions) are assigned one or more of The International Classification of Diseases-Clinical Modification (ICD-CM) codes (7–10 editions) or Current Procedural Terminology (CPT) codes that are used for billing and administrative purposes. Clinical and epidemiological studies often rely on ICD-CM codes found in large administrative databases to define patients as having CP. The reliability of these diagnoses within various medical databases is often uncertain¹⁸ and “messy”¹⁹ because validation of the ICD-CM codes by performing a manual chart review is infrequent. Indeed, misclassification of CP is substantial and ranges 16–52% among several registry/large database studies that confirm the accuracy of the diagnosis by manual chart review.^{20–22} Data from these studies raise the surprising possibility that the accuracy of ICD-CM coding is substantially worse at a tertiary care institution compared to population or national databases, but the former is based on analysis of only 60 patients. Furthermore, if misclassification is large, it is imperative to understand the cause(s) of misclassification so errors in coding can be decreased and accuracy of databases improved. Based on these data, assessing the accuracy of a database should be considered a prerequisite for initiating epidemiological studies, attempting to compare data from epidemiologic studies and for generating feasibility data to develop clinical programs and to design clinical research studies.¹⁸

This study arose because it was necessary to determine the number of CP patients who could be available to recruit into a University of Michigan randomized controlled trial, entitled *Pioglitazone therapy for endocrine and exocrine disease in alcoholic pancreatitis* (ClinicalTrials.gov Identifier: NCT00782795). In a preliminary assessment we found that a number of patients with the ICD-9-CM code 577.1 for CP did not have definite-CP according to clinical diagnostic criteria. Therefore we hypothesized that the ICD-9-CM code 577.1 for CP is inaccurate. To investigate this hypothesis we performed a retrospective chart review of all patients with an ICD-9-CM code 577.1 between 10/01/05–11/01/08 and determined if they met one or more of three clinical diagnostic criteria for definite-CP: Japanese Pancreas Society (3rd version),¹² Ammann’s (Zurich Workshop) Criteria,^{11, 23} and the Mayo Scoring System.^{10, 24} We then examined whether patients in the “Non-CP” group (who did not fulfill clinical diagnostic criteria of definite-CP) had abnormal imaging and/or

a history of recurrent attacks of pancreatitis that might suggest misclassification as Non-CP due to overly stringent diagnostic criteria.

MATERIALS AND METHODS

Administrative database and selection of case samples

The study was approved by the University of Michigan Institutional Review Board. The University of Michigan is a tertiary care referral center. Annually, the Emergency Department has >81,000 visits and the 919-bed hospital has >45,000 admissions and >4,500 annual discharges from its GI and GI surgery services. We performed an information data exchange (IDX) cross-sectional search of our health system's databases (see Figure 1) and identified 1,343 unique patients age 18 years or older who had an International Classification of Diseases 9th edition (ICD-9) code (577.1) for CP between October 1, 2005 and November 1, 2008. Patients were assigned as having definite-CP (n=658) or Non-CP (n=685) based on whether any of the 3 clinical diagnostic criteria (the study gold standard) were fulfilled (see Table 1).

Data collection, variables and definitions

Co-investigators NGR, SN and MJD used methods similar to our previous studies²⁵ to search the entire electronic medical record for data of interest, to reconcile variations in the data recorded in the electronic health record, and to collect and tabulate data with Microsoft Excel (Microsoft, Redmond, Wash) spreadsheets for data management. Standardized data collection forms were completed by collecting data for age, gender, cigarette smoking, alcohol use and criteria for CP (see Table 1). We defined cigarette smoking and alcohol use as ever vs never because information regarding the amount and duration of exposures was commonly absent or uncertain and inadequate for analysis. Data collection involved extracting data from chart notes (Gastroenterology clinic visits, inpatient consults and emergency department visits); and laboratory reports to determine whether patients had abdominal pain, weight loss, steatorrhea (>7 grams fat/24 hours), Atlanta criteria for acute pancreatitis,²⁶ diabetes mellitus (fasting blood glucose ≥ 126 mg/dL), exocrine pancreatic function testing and pancreatic histology. Data for the latter two variables was available infrequently in the CP (n=658) and Non-CP (n=685) groups: 119 had qualitative or quantitative fecal fat testing (10.3% CP vs 7.4% Non-CP), 32 had direct exocrine pancreatic function testing (2.4% CP vs 2.3% Non-CP) and 51 had pancreatic histology (7.7% CP vs 0% Non-CP). In addition we obtained pancreatic imaging evidence of CP from ERCP, transabdominal ultrasound and cross-sectional CT or MRI that met Cambridge II-III⁷⁻⁹ criteria (defined as having at least 3 abnormal pancreatic duct side-branches plus an abnormal appearing main pancreatic duct), and from endoscopic ultrasound reports that met 5 EUS criteria.^{27, 28} To collect this data, the study team reviewed reports for all imaging studies performed within 12 months of the medical record review.

Statistical Analyses

Categorical and dichotomous variables were assessed by 2x2 contingency tables and χ^2 -tests or two-tailed Fisher's exact test when necessary. Continuous variables were assessed by two-sample t-tests for normally distributed variables and the Wilcoxon rank-sum test for

non-parametric data. Statistical significance was defined as $P < 0.05$. Statistical analyses were performed using JMP version Pro 8.0 (SAS Institute, Cary, NC).

RESULTS

Study patients and accuracy of CP diagnosis

1,343 patients had an ICD-9-CM code 577.1 for CP. Only 658 (49%) fulfilled one or more of the three gold standard clinical diagnostic criteria for definite-CP and 685 (51%) did not fulfill any of these criteria ("Non-CP").

Prevalence of CP defined by applying 3 sets of clinical diagnostic criteria

All patients who met clinical diagnostic criteria for definite-CP fulfilled the Mayo Scoring system criteria (Table 2). Secondly, there was strong agreement among the 3 clinical diagnostic criteria for definite-CP. Specifically, 84% of patients in the definite-CP group met all 3 clinical diagnostic criteria for CP (Table 2). Fewer patients fulfilled only one criterion (9.0%) or two criteria (6.7%).

Possible misclassification of the Non-CP group

Abnormal imaging (Table 3) and recurrent attacks of pancreatitis (Table 4) raise the possibility of underlying CP that does not fulfill any of the gold standard clinical diagnostic criteria. Of the Non-CP group 93.7% had at least one pancreatic imaging test (Table 3) and 39 (5.7% of 685) met imaging criteria for CP without fulfilling any of the clinical diagnostic criteria. They included 28 who had EUS scores greater than or equal to 5, six with Cambridge scores ranging II-III, and five with an abnormal EUS plus an abnormal cross-sectional imaging study.

Almost half (48.6%) of the Non-CP group ($n=685$) had recurrent attacks of pancreatitis compared to 86.2% in the CP group ($P<0.0001$; Table 4). Other significant differences between the two groups were that the CP had a modestly higher mean (SD) age (54.1 ± 15.6 vs 51.5 ± 16.4 ; $P=0.030$), a higher percentage of men (56.1% vs 45.8%; $P<0.001$) and an expected higher frequency of manifestations of CP (chronic abdominal pain, recurrent pancreatitis, weight loss, steatorrhea, diabetes mellitus and pancreatic calcifications) or pancreatitis risk factors (ever smoking and ever drinking; Table 4)

The Non-CP group had heterogeneous and often multiple (>1) diagnoses in the medical record. Over 50% of patients had diagnoses associated with chronic pain, which in many instances might represent a chronic pain syndrome, including 137 (20%) with chronic abdominal pain; 52 (7.6%) with irritable bowel syndrome or functional dyspepsia; and 121 (17.7%) with "recurrent acute pancreatitis". Additional diagnoses included 325 persons (47.4%) with acute pancreatitis, 52 (7.6%) with pancreatic adenocarcinoma, 33 (4.8%) unclear/not known, 15 (2.2%) referred for imaging only and 10 (1.5%) with pancreatic hyperenzymemia <3 -fold the upper limits of normal.

DISCUSSION

Our main finding was that 51% of patients with the ICD-9-CM code 577.1 failed to meet established criteria for definite-CP. In our group of 1,343 patients with the ICD-9-CM code for CP, only 658 (49%) met at least one of the three gold standard clinical diagnostic criteria for definite-CP. All patients with definite-CP fulfilled the Mayo criteria and greater than 84% of patients with definite-CP met all 3 diagnostic criteria, suggesting each of these clinical diagnostic criteria is useful for classifying patients as having definite-CP but there is a trend towards greater sensitivity of the Mayo criteria (possibly because Mayo but not Ammann or JPS includes diabetes as a diagnostic criterion).

In several prior studies investigators performed manual chart reviews of small subsets of patients and reported the inaccuracy of ICD-CM derived diagnoses for CP; misclassification (inaccuracy) varied from 16–19% in national registries^{20, 21} and 25–51% in health system databases.²² Besides the possibility that the type of database may cause differences in accuracy, other differences among studies that might account for variable accuracy include the diagnostic gold standard employed, geography, the ICD-CM edition and the study sample size. Among these variables, however, the nature of the diagnostic gold standard appears to be the most important.

Selection of the gold standard (in our study Mayo, Ammann, JPS and combination of all 3) and the stringency of the diagnostic criteria may greatly affect misclassification. For example, as noted above we found small but a significant difference among these 4 standards for diagnosis of definite-CP (accuracy of ICD-9-CM CP codes ranged 42.1–49%). As a clear illustration of how stringency of diagnostic criteria can affect inaccuracy, other investigators used the M-ANNHEIM diagnostic criteria for CP,¹³ which is a modification of Ammann's,^{11, 23} and graded CP as borderline, probable, or definite. They found that ICD-9-CM code inaccuracy for CP increased from the less stringent to the more stringent grades (25% for any of 3 grades; 33% for the combined probable and definite grades, and 52% for the definite grade alone). Their definite grade inaccuracy is similar to our 51% definite-CP inaccuracy for our tertiary care center database.

Also similar to the data of Schneider et al.,¹³ we found that applying less stringent criteria would result in a decreased rate of inaccuracy for the ICD-9-CM CP code. In our study, 39 persons (5.7%) of the Non-CP group had imaging criteria for CP (28 with EUS 5 criteria, 6 with Cambridge II-III, and 5 with both), but according to our definitions lacked additional criteria to establish definite-CP. But even if we assume these patients had CP, 52% of persons with the ICD-9-CM code would have had definite-CP ($658+37=695/1343 \approx 52\%$), only a 3% reduction of the error rate from 51 to 48%. These findings suggest that while the clinical scoring systems are specific for characterizing patients as having definite-CP, they may lack sensitivity, as patients might have subclinical (painless) CP.

Painless, subclinical CP needs to be distinguished from painless definite-CP, a puzzling phenotype Bartholomew recognized and described in 1956. These patients lack pain but have pancreatic calcifications, steatorrhea and diabetes mellitus.²⁹ Others have estimated frequencies of painless definite-CP ranging 0–40% in patients with heterogeneous etiologies

of CP,³⁰ 5–16% for alcoholic CP,^{10, 31} and 50% for late-onset (or senile) idiopathic CP.^{10, 31} The existence of painless definite-CP is also suggested on the basis of histologic findings of CP at autopsy, but in life there was no clinical indication of CP.³²

The Non-CP group is heterogeneous. Over 50% have diagnoses associated with chronic pain (chronic abdominal pain, irritable bowel syndrome or functional dyspepsia, or “recurrent acute pancreatitis”), which in many instances might represent a chronic pain syndrome. In contrast to our imaging data indicating a small percentage of the Non-CP may have CP, nearly half of the Non-CP group had recurrent attacks of pancreatitis and may have had CP. We speculate some of these patients had chronic relapsing pancreatitis (CRP), a term coined by Comfort² for a CP phenotype subsequently characterized in natural history studies of alcohol and idiopathic CP by Ammann et al.^{33, 34} and Layer et al.¹⁰ CRP is relapsing episodes of painful attacks during the early course of CP with few if any hallmarks of established CP (ECP) and should be distinguished from the term “recurrent acute pancreatitis” (RAP), which “should be reserved for identifiable causes of acute pancreatitis that do not lead to CP if the causes (e.g. gallstones, hypertriglyceridemia etc.) are treated” (see recent review³⁵). Distinguishing between the two CP phenotypes (CRP and ECP) and between CRP and RAP is essential to establish unambiguous associations with risk factors (environmental, genetic etc.), response to therapy, etc. in CP. Although we don’t have information to definitively exclude causes of RAP, if we assume persons in the Non-CP group with “recurrent pancreatitis” had CP $[(0.486 \times 685) + 658]/1343 \approx 74\%$, 74% of the 1343 patients with an ICD-9-CM CP code would have a diagnosis of CP (inaccuracy = 26%). Finally, combining the possible misclassification rates from imaging data and presence of “recurrent pancreatitis”, 77% of the Non-CP group $(658+37+333=1028; 1028/1343 \approx 77\%)$ with an ICD-9 CP code would have an inaccuracy of rate of 23%.

Thus, these data emphasize that application of stringent clinical diagnostic criteria for CP maximizes certainty of diagnoses, promotes accurate reporting of health care parameters and epidemiology of disease, allows reliable planning for health care and clinical research, and permits comparisons with other validated datasets. A pitfall is some patients may be misclassified as not having CP due to incomplete data (e.g. imaging data was absent in 6.3% of the Non-CP group) or having early disease with recurrent attacks of pancreatitis but absent overt manifestations of CP.

Of the other variables, geography, perhaps because of different coding expertise among physicians and/or coding staff, may affect accuracy of coding, but ICD-CM edition is less likely to do so. Among European and North American studies accuracy differs significantly. For example Danish²¹ and Dutch²⁰ investigators report a similar database inaccuracy <20% for their respective national registries. The Danish investigators²¹ reported an inaccuracy of 19% in 719 patients, but detailed diagnostic data is not provided and a separate Danish study published the same year reported inaccuracy (in much smaller numbers of patients [54–67]) varied from 22–37% over time.³⁶ In contrast to the European studies, Tignor et al.²² examined a large North American health system database (Partners Research Patient Data Registry) and reported a greater inaccuracy range of 25% to 52% in 60 patients, mirroring our findings. Unlike the geographic difference in accuracy, use of the 8th and 10th edition

ICD-CM by the Danes²¹ and ICD-9 by the Dutch²⁰ did not seem to affect accuracy of coding.

The definite-CP and Non-CP groups differ in several ways. The definite-CP group had a higher frequency of CP criteria, ever-smoking (57.3% vs 47.3%) and ever drinking alcohol (64.1% vs 54.9%), and was older and had more men. Unfortunately, quantitative data for smoking and drinking (both amount and duration) was commonly missing and precluded analyses that would measure the strength of the relationship between these exposures and the CP vs Non-CP groups.³⁷ These findings suggest, however, that older persons, men, and users of tobacco and alcohol are more likely to meet clinical diagnostic criteria for definite-CP.

Limitations of the study include a retrospective study design used to gather feasibility data to design a prospective clinical trial, misclassification of Non-CP due to incomplete diagnostic data, CP underreporting, and referral bias. Incomplete diagnostic data, including rare measurement of exocrine pancreatic insufficiency (e.g. fecal fat testing 7.4%) and a modest deficiency (6.8%) of any available imaging studies in the Non-CP group, may have led to an erroneous diagnosis of Non-CP. Underreporting of CP has been described due to misclassification of patients with CP coded as having acute pancreatitis. Misclassification of acute pancreatitis coding is generally 20%^{20, 38–41} but may vary by year (27–49%)³⁶ and 5–13% of patients coded as acute pancreatitis have CP.^{20, 38} Additionally, under- and over-reporting and misclassification stem from imprecise clinical documentation, limited medical knowledge of the coding staff and coding of diseases that are more difficult to recognize and diagnose^{42, 43} like CP, particularly in a tertiary care center where referral of complex patients challenge diagnostic or management decisions. Lastly we used the ICD-9-CM code and the initiation of the more precise ICD-10-CM across the United States may translate to more accurate coding of comorbid illnesses.⁴⁴ It is likely, however, that ICD-10-CM coding for CP will remain inaccurate as the combined 8th and 10th edition ICD-CM codes for CP of the Danish national registry had an inaccuracy of 19% for CP.

In summary, the diagnosis of CP by ICD-9-CM code (577.1) may be less than 50% accurate for definite-CP based on three clinical diagnostic criteria as the gold standard(s). The three clinical diagnostic criteria define definite-CP but may underestimate CP when only symptoms are present, particularly when testing and long-term follow-up are incomplete. Hence, using ICD-9-CM code (577.1) as the sole basis for diagnosis of CP may contribute to erroneous epidemiological data and conclusions as it may overestimate CP diagnoses. The implications for epidemiological studies are that the ICD-9-CM (577.1) code for CP is suitable as a screening test but data reporting should involve the application of clinical diagnostic criteria as the gold standard to categorize patients as having definite disease (established CP) or possible disease based on symptoms or imaging alone (chronic relapsing pancreatitis). These data emphasize that validation of ICD-CM codes is critical for any retrospective study of CP. An alternate approach to retrospective evaluation of datasets is to plan future epidemiologic studies that prospectively captures patients, a more labor-intensive and costly approach.

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Abbreviations

AP	acute pancreatitis
CI	confidence interval
CP	chronic pancreatitis
CPT	Current Procedural Terminology
CRP	chronic relapsing pancreatitis
CT	computed tomography
ECP	established chronic pancreatitis
ERCP	endoscopic retrograde cholangiopancreatography
EUS	endoscopic ultrasonography
ICD-CM	International Classification of Diseases-Clinical Modification
JPS	Japanese Pancreas Society
MRCP	magnetic resonance cholangiopancreatography
RAP	recurrent acute pancreatitis
US	ultrasonography

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Figure 1.
Methodological Summary

Table 1

Three clinical diagnostic criteria for definite chronic pancreatitis

Criteria	Definition
Japanese Pancreas Society (JPS) 3rd version definite clinical diagnostic criteria	
<i>Clinical criteria</i>	Chronic pain, RAP, weight loss or oily stools
<i>Plus > 1 of the following</i>	
•Calcifications	CT or US
•Histology	
•Abnormal imaging	Cambridge II-III (<i>or</i> ≥ 5 EUS criteria)
•Secretin test	Low [HCO ₃ ⁻] <i>plus</i> low [enzyme] or volume
Ammann's (Zurich Workshop) definite clinical diagnostic criteria	
<i>Clinical criteria</i>	RAP
<i>Plus > 1 of the following</i>	
•Calcifications	X-ray, CT or US
•Histology	
•Abnormal imaging	Cambridge II-III (<i>or</i> ≥ 5 EUS criteria)
•Steatorrhea	>7 g fat/24 hrs (>2 years) & response to pancreatic enzyme replacement
Mayo scoring system – definite clinical diagnostic criteria)	
	Points
<i>Six-component scoring system (requires 4 points for diagnosis)</i>	
•Clinical criteria	Chronic pain, RAP or weight loss
•Calcifications	Definite / probable
•Histology	Definite / probable
•Abnormal imaging	Cambridge II–III (<i>or</i> ≥ 5 EUS criteria)
•Exocrine pancreatic function	Pancreatic steatorrhea (qualitative or quantitative) Abnormal CCK PFT
•Diabetes mellitus	Fasting blood glucose > 126 mg/dL

CCK, cholecystokinin; CT, computed tomography, EUS, endoscopic ultrasonography; PFT, pancreatic function testing; RAP, recurrent acute pancreatitis, US, ultrasound

Japanese Pancreas Society (3rd version),¹² Ammann's (Zurich workshop) Criteria,^{11, 23} and the Mayo Scoring System.^{10, 24} Cambridge II–III criteria.^{7–9}

Table 2

The prevalence of chronic pancreatitis defined by applying 3 sets of clinical diagnostic criteria

Criteria	No of Patients	%	95% CI
<u>Individual Criteria</u>			
Japanese Pancreas Society (JPS)	588/1343	43.8%	41.1–46.4
Ammann's (Zurich Workshop) criteria	566/1343	42.1%	39.5–44.8
Mayo Scoring system	658/1343	49.0%	46.3–51.7
<u>Pooled Criteria</u>			
1 Criterion	59/658	9.0%	6.8–11.1
2 Criteria	44/658	6.7%	4.8–8.6
3 Criteria	555/658	84.3%	81.6–87.1

CI, confidence interval.

Table 3Possible misclassification of non-chronic pancreatitis group *based on abnormal imaging*

Criteria	No of Patients	%
Any available imaging (CT, MRI, ERCP, US or EUS)	642/685	93.7%
Imaging criteria suggested chronic pancreatitis	39/685	5.7%
EUS score ≥ 5	28/685	4.1%
<u>Other imaging</u>		
Non-diagnostic imaging n=17 (11 CTs, 6 MRIs)		
No other imaging n=11		
Cambridge II–III (4 CTs, 1 ERCP, 1 MRI)	6/685	0.9%
EUS score < 5 n=3		
No EUS n=3		
EUS <i>plus</i> CT (n=4) or MRI (n=1)	5/685	0.7%

CT, computed tomography; EUS, endoscopic ultrasonography; ERCP, endoscopic retrograde cholangiopancreatography; MRI, magnetic resonance cholangiopancreatography; US, ultrasound

Cambridge II–III criteria.^{7–9}

Table 4Possible misclassification of non-chronic pancreatitis (CP) group *based on recurrent pancreatitis*

Variable	Definite-CP	Non-CP	P-value
Patients	658	685	
Mean (SD) age, yrs	54.1 (15.6)	51.5 (16.4)	0.003
Women (%)	43.9%	54.2%	< 0.001
Chronic abdominal pain (%)	86.5%	63.5%	< 0.001
Recurrent pancreatitis (%)	86.2%	48.6%	< 0.001
Weight loss >10 kg (%)	31.4%	16.3%	< 0.001
Steatorrhea (%)	6.5%	0.7%	< 0.001
Diabetes mellitus (%)	35.0%	17.2%	< 0.001
Pancreatic calcifications (%)	42.9%	0%	< 0.001
Ever smoking cigarettes (%)	57.3%	47.3%	< 0.001
Ever drank alcohol (%)	64.1%	54.9%	0.003

Statistics: Fisher exact test for categorical variables.

CP, chronic pancreatitis; SD, standard deviation.