

**Positive Predictive Value of Acute and Chronic Pancreatitis Diagnoses in the Danish
National Patient Registry: A Validation Study**

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ABSTRACT

Aims

To examine the validity of acute and chronic pancreatitis diagnoses registered in the Danish National Patient Registry (DNPR).

Methods

In the DNPR, we identified all patients admitted to two Danish hospitals with acute or chronic pancreatitis from 1996 through 2013. From this population, we randomly sampled 100 patients with acute pancreatitis and 100 patients with chronic pancreatitis. For each cohort, we computed positive predictive values (PPVs) and associated 95% confidence intervals (CIs) for the discharge diagnosis of acute or chronic pancreatitis, using medical records as gold standard.

Results

We identified 2,617 patients with acute pancreatitis and 1,284 patients with chronic pancreatitis discharged from either of the two hospitals during the study period. Of these, 776 (19.9%) had a diagnosis of both acute and chronic pancreatitis and thus present in both cohorts. From the 200 sampled patients, a total of 138 (69.0%) medical records were available for review. The PPV for a diagnosis of acute pancreatitis in the DNPR was 97.3% (95% CI: 90.5%-99.2%) and for chronic pancreatitis 83.1% (95% CI: 72.2%-90.3%).

Conclusions

The validity of acute and chronic pancreatitis diagnoses registered in the DNPR is generally high since 1996.

Keywords

Acute pancreatitis; chronic pancreatitis; Danish National Patient Registry; validation study

Word count

2,750

BACKGROUND

Acute and chronic pancreatitis are common diseases and associated with significant public health-care burdens worldwide.[1, 2] Aside from the severity of these conditions, both diseases can progress to pancreatic cancer,[3, 4] one of the most aggressive malignancies with a dismal prognosis.[5] Due to the high morbidity and mortality from pancreatic diseases, further research into this field is vital.

Registry-based research is important to facilitate large-scale population-based studies with long-term follow-up, but the quality of registry-based research depends on the validity of the recorded information. In Denmark, all hospitalizations have been continuously registered in the Danish National Patient Registry (DNPR) since 1977.[6] The validity of pancreatitis diagnoses in the DNPR have previously been investigated in three studies with positive predictive values (PPVs) ranging from 50-91% depending on hospital, year of diagnosis, and type of pancreatitis.[7-9] However, two of these studies were limited by misclassification of the diagnostic codes used to classify pancreatitis,[7, 8] and one study examined only postmenopausal women with osteoporosis thereby limiting generalizability.[9] Furthermore, during the years examined in some of these studies, a new version of the International Classification of Diseases (ICD) was introduced. Diagnostic criteria for acute and chronic pancreatitis have also varied and been widely debated during the years as a result of new knowledge and improved diagnostic methods.[10] Thus, findings from the early calendar periods may not be applicable to later periods.

In the present study, we aimed to assess the validity of acute and chronic pancreatitis diagnoses in the DNPR using medical record review as a gold standard. As a secondary aim, we examined if the prevalence of self-reported alcohol abuse and tobacco smoking correlates with the registration of selected alcohol- and smoking-related diagnoses in the DNPR. Alcohol consumption and tobacco smoking are common among pancreatitis patients,[11] but

are not routinely registered in the DNPR. Both may act as potential confounders in epidemiological studies. Thus, valid tools to control for exposure to these substances (*e.g.* through proxy diagnoses such as esophageal varices and chronic obstructive pulmonary diseases) would be valuable.

METHODS

Setting

Denmark is divided into five regions, which are comparable with respect to hospital structure and health-care utilization.[12] This is, in part, owing to the uniform health-care system in Denmark, which offers free and equal access to medical treatment for all residents. Our study was conducted at two hospitals (Aarhus University Hospital and Randers Regional Hospital) within the Central Denmark Region, which covers approximately 20% of the entire Danish population.

The Danish National Patient Registry

At hospital discharge, details about the patient's hospital contact and concomitant diagnoses are registered in the DNPR, which was established in 1977.[13] Since 1995, information on all emergency room and outpatient visits has also been registered in the DNPR. Each hospital contact is registered with one primary discharge diagnosis (A diagnosis) and up to 20 secondary discharge diagnoses (B diagnoses). The discharge diagnoses are registered according to the ICD 8th revision (ICD-8) from 1977 to 1993 and 10th revision (ICD-10) hereafter.

Study population

We identified all patients in the DNPR with their first discharge diagnosis of either acute or chronic pancreatitis from one of the two hospitals during the period 1 January 1996 to 31 December 2013. We chose this time period for two reasons. First, to allow a lag-period following the change in ICD coding from ICD-8 to ICD-10 in 1994. Second, this time period is relevant to future research projects from our group on the association between pancreatitis and pancreatic cancer risk and prognosis. Patients were identified using the ICD-10 codes for acute (DK85) and chronic (DK860, DK861) pancreatitis. As patients with chronic pancreatitis often present with recurrent acute pancreatitis, some patients appeared in both cohorts. Due to the severe pain that accompanies acute pancreatitis, we excluded outpatient diagnoses of acute pancreatitis, as these are most likely due to either misclassification or outpatient follow-up visits following a hospitalization.

For each patient, we retrieved all diagnoses of selected alcohol- and smoking-related diseases to examine the proportion of patients with a self-reported use of these substances having a diagnosis of alcohol- or smoking-related disease in the DNPR. For alcohol, we selected seven different conditions (alcoholism, alcoholic liver disease, alcoholic cardiomyopathy, alcoholic polyneuropathy, alcoholic gastritis, alcoholic pancreatitis, and esophageal varices), whereas we selected chronic obstructive pulmonary disease and emphysema as smoking-related conditions. See supplementary material for relevant ICD codes (Table S1).

We restricted our study to two Danish hospitals – Aarhus University Hospital and Randers Regional Hospital and divided the study period into five calendar periods (1996-1999, 2000-2003, 2004-2007, 2008-2010, and 2011-2013). From each stratum, we randomly sampled 5 acute and 5 chronic pancreatitis patients to yield a total study population of 100 acute and 100 chronic pancreatitis patients.

Review of medical records

To validate the diagnoses of acute and chronic pancreatitis in the DNPR, we used medical record review as the gold standard. The medical records were reviewed by four of the authors (JK, FVM, MRM, and IRJ). For each patient, we assessed if the diagnosis registered in the DNPR was correct based on the information on clinical, laboratory, and radiological findings reported in the medical records. A diagnosis was considered to be correct if the diagnostic criteria were fulfilled. Acute pancreatitis was defined as at least two of the following three criteria: 1) upper abdominal pain, 2) blood amylase levels >3 times the upper normal limit, and 3) radiological findings characteristic for acute pancreatitis. Chronic pancreatitis are diagnosed according to modified Mayo-criteria, which are described elsewhere.[14] In brief, these include radiological and histological findings, typical pain, and exocrine or endocrine insufficiency. In case of any doubt about the validity of the diagnoses based on information from the medical record, an expert in pancreatic diseases (FVM) was consulted. We also extracted information on self-reported alcohol abuse (defined as >7 drinks per week for women and >14 drinks per week for men; classified as current, former, or never) and tobacco smoking (current, former, or never) from the medical records. We only considered information on exposure to these substances recorded during the admission at which the patient was diagnosed with pancreatitis. Data from the medical records were entered into REDCap.[15]

Statistical analyses

We present descriptive characteristics of all patients diagnosed with acute and chronic pancreatitis at either of the two hospitals and the validation study subset of patients. We computed the PPV and corresponding 95% confidence interval (CI) for each diagnosis. The PPV was calculated as the number of correct diagnoses divided by the total number of

diagnoses in the sample. We stratified the patients by age group, sex, calendar period, and hospital and then computed the PPV for each stratum. In addition, we calculated the % agreement of having an alcohol- or smoking-related diagnosis in the DNPR given an actual exposure to these substances, reported in the medical records. The % agreement was calculated based on patients in whom drinking and smoking status could be assessed. Patient sampling and statistical analyses were performed using Stata 13.1 (StataCorp LP, College Station, Texas, US).

Sensitivity analysis

To examine if the validity of pancreatitis diagnoses in patients with both acute and chronic pancreatitis differed compared with patients with only one of those diagnoses, we conducted a sensitivity analysis, restricting to patients with only one of those diagnoses.

Ethical considerations

This study was approved by the Danish Data Protection Agency (Case no. *1-16-02-402-16* and J.nr. *2012-58-006*), the Danish Patient Safety Authority (J.nr. *3-3013-1760/1*), and the head of the surgical departments at the two hospitals.

RESULTS

Sampling and medical record review

We identified 2,617 patients with acute pancreatitis and 1,284 patients with chronic pancreatitis, diagnosed at one of the two hospitals during the study period (Table 1). Of these, 776 (19.9%) had a diagnosis of both acute and chronic pancreatitis and are thus present in both cohorts. We were able to obtain the medical records of 138 patients (69.0%) of the 200

patients in the sample. The unobtainable medical records were physically missing from the medical records archives. The patients whose medical records could be obtained were similar to the sampled population with respect to age, sex, alcohol- and smoking-related diagnoses, and type of hospital. Medical records from patients diagnosed in the earliest calendar period of the study were less frequently obtained (Table S2).

Acute pancreatitis

The median age at diagnosis was 55.8 years and the majority were men (53.7%). A higher proportion of acute pancreatitis patients (65.5%) were admitted to the university hospital. The patients were equally distributed across calendar periods (Table 1). Of the 100 patients sampled, 73 medical records could be retrieved. The overall PPV for an acute pancreatitis diagnosis in the DNPR was 97.3% (95% CI: 90.5%-99.2%) with no major differences between age groups, sex, hospital, or calendar period (Table 2). In the DNPR, 34.0% had an alcohol-related diagnosis, and 15.0% had a smoking-related disease. In the medical records, 34.3% had evidence of current or former alcohol abuse, whereas approximately half (49.3%) were current or previous smokers. Of 25 patients reporting an alcohol abuse, 19 (76.0%) had an alcohol-related diagnosis. Among the 36 patients who reported to be smokers, 10 (27.8%) had a smoking-related diagnosis in the DNPR (Table 3).

Chronic pancreatitis

Among patients with chronic pancreatitis, the median age was 53.7 years and more than two-thirds were men (69.5%). Most patients (77.7%) were diagnosed at the university hospital and in the earliest calendar period (Table 1). We could obtain 65 medical records out of the 100 patients sampled. Overall, the PPV for a diagnosis of chronic pancreatitis was 83.1% (95% CI: 72.2%-90.3%). Patients younger than 40 years and those diagnosed in the period 2008-

2010 had a slightly lower PPV compared with the rest of the population (Table 2). A total of 70.0% of the chronic pancreatitis patients had an alcohol-related diagnosis registered in the DNPR, and 16.0% had a smoking-related diagnosis. Approximately two-thirds (69.2%) had evidence of current or former alcohol abuse in the medical records, whereas 77.0% were current or previous smokers. Of 45 patients reporting an alcohol abuse, 39 (86.7%) had an alcohol-related diagnosis. Among the 50 patients who reported to be smokers, seven patients (14.0%) were registered in the DNPR with a smoking-related diagnosis (Table 3).

Sensitivity analysis

Our sensitivity analysis did not substantially affect our estimate for either acute (PPV: 96.7%; 95% CI: 88.6%-99.1%) or chronic (PPV: 84.4%; 95% CI: 68.2%-93.1%) pancreatitis.

DISCUSSION

In the present study, we demonstrate that the validity of the discharge diagnoses for acute and chronic pancreatitis registered in the DNPR is generally high and sufficient for use in registry-based research since 1996. The overall PPV for acute pancreatitis was 97.3% and for chronic pancreatitis 83.1%. In general, the PPVs were consistently high when stratifying by age group, sex, hospital, and calendar period.

Our study extends the previous findings on the validity of pancreatitis diagnoses in the DNPR.[7-9] Floyd and colleagues found a PPV for acute pancreatitis diagnoses of 82% during 1981-2000, which concurs with our PPV of 85.7% in the period 1996-1999.[7] Their PPV is lower than our overall estimate, which may be explained by improvements in imaging modalities in the later years. This is supported by the fact that they validated an additional

subset of 90 women diagnosed with acute pancreatitis in 1997 and 1999, finding a PPV of 91%.

Nøjgaard et al. validated patients discharged with acute or chronic pancreatitis from a single hospital in Copenhagen in the years 1983, 1994, and 2005.[8] They found lower PPVs than us, as no PPV in their study exceeded 78.1%. Part of this difference may be attributed to the fact that they failed to include some of the ICD codes for both acute and chronic pancreatitis. Furthermore, they extended their definition of chronic pancreatitis to include ICD codes used to classify pancreatic pseudocysts, which can be related to both acute as well as chronic pancreatitis, and pancreatic diseases not related to chronic pancreatitis such as pancreatic cysts and pancreas divisum. Thus, misclassification of pancreatitis may have led to the lower PPVs in their study. We only considered inpatient records of acute pancreatitis. It is unclear, if the study by Nøjgaard included outpatient visits as well. If so, this may also explain their lower PPVs due to possible misclassification. Some of the differences may also be explained by improved diagnostics during the years, as we assessed patients diagnosed during 1996-2013. However, this contrasts with our finding of a slightly lower PPV of chronic pancreatitis in the period 2008-2010 compared to the start of the study period. It seems unlikely that the quality of diagnostic workup in chronic pancreatitis patients has decreased over time. Furthermore, the PPV in the subsequent period (2011-2013) was similar to the PPV in the first calendar periods. As such, chance may have caused this finding, as numbers in the different calendar periods are relatively small.

Munch et al. validated acute pancreatitis diagnoses in 42 postmenopausal women with osteoporosis admitted to a hospital in the Central Denmark Region during the period 2006-2014.[9] They found a PPV of 82.5%, which is lower than our finding. However, there are some differences between our studies. First, to be classified as a correct diagnosis, they required that acute pancreatitis was the primary cause for hospitalization, whereas we

considered both primary and secondary diagnoses. Second, their study was confined to a very restricted study population - namely postmenopausal women with osteoporosis - thus results may not be generalizable to other populations.

As a secondary aim, we sought to examine if selected medical conditions can serve as proxy diagnoses for alcohol consumption and tobacco smoking among pancreatitis patients, as exposure to these substances is not routinely registered in the DNPR.[16] As confounding due to alcohol and tobacco can lead to spurious associations, methods to control for these substances are important. Among patients in this study, our selected alcohol-related conditions were a good proxy of actual alcohol abuse with high percent agreements. Smoking-related diagnoses, however, did a poor job in capturing actual exposure to tobacco smoking for patients with acute or chronic pancreatitis. This inability of the DNPR to capture tobacco smoking is supported by previous work.[16] However, we suggest that these results are interpreted with caution due to the high risk of patients underreporting their use of tobacco smoking and alcohol consumption in medical records.

A major strength of our study is the use of prospectively collected DNPR data, ensuring that we were able to sample from the all hospitalizations throughout the Central Denmark Region, limiting the possibility of selection bias. Some limitations should be considered when interpreting our results. First, a major limitation of our study is that 31% of the medical records were missing from the medical record archives. This is identical to the retrieval rate in the study by Munch et al.[9] However, when examining the patients' baseline characteristics between those in the sample and those with an obtainable record, no major differences were evident. The medical records from the earliest calendar period of the study were more often missing compared with the later years. This may have led to an overestimation of the PPV due to improved diagnostics in the later years, which is also suggested by our lower PPV in the first period. However, this estimate was based on very low

numbers (13 patients in total). We note a slight discrepancy regarding the distribution of age between the entire acute pancreatitis population and our sampled population. However, as the PPVs were consistently high irrespective of age group, we consider the missing records unlikely to have introduced major selection bias in our study. Second, we considered only patients admitted to two hospitals in the Central Denmark Region. This may imply that the results are not generalizable outside the region. However, Denmark is a country with a homogenous population with respect to the use of health-care across all five regions.[12] Further, the uniform tax-financed health-care system ensures free and equal access to hospitals for all Danish residents. We therefore find it likely that these results are transferrable to other Danish regions.

The high PPVs found in this study confirm that the DNPR is a valuable source in registry-based research of acute and chronic pancreatitis. The distribution of age and sex as well as prevalence of alcohol-related conditions in our study population compares to previous reports on the natural history of these diseases, adding weight to our conclusion that the population examined in this study is in fact a population affected by pancreatitis.[17-21]

CONCLUSIONS

In conclusion, the validity of acute and chronic pancreatitis registered in the DNPR is generally high since 1996. Our selected alcohol-related conditions performed well as a proxy for actual alcohol abuse, whereas the selected smoking-related conditions were not representative of tobacco smoking.

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DECLARATION OF CONFLICTING INTERESTS

The Authors declare that there is no conflict of interest

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Table 1. Descriptive characteristics of patients registered with acute or chronic pancreatitis in the Danish National Patient Registry, diagnosed at Aarhus University Hospital or Randers Regional Hospital in the period 1996-2013.

	Acute pancreatitis		Chronic pancreatitis	
	N	%	N	%
All patients	2,617	100%	1,284	100%
Median age, years (range)	55.8 (18.4-98.6)		53.7 (18.0-92.8)	
Age group				
<40 years	539	20.6%	161	12.5%
40-49 years	464	17.7%	333	25.9%
50-59 years	514	19.6%	382	29.8%
60-69 years	450	17.2%	263	20.5%
+70 years	650	26.8%	145	11.3%
Sex				
Men	1,405	53.7%	892	69.5%
Women	1,212	46.3%	392	30.5%
Alcohol-related diagnosis	676	25.8%	858	66.8%
Smoking-related diagnosis	297	11.4%	212	16.5%
Hospital				
University Hospital	1,713	65.5%	997	77.7%
Regional Hospital	904	34.5%	287	22.3%
Calendar period				
1996-1999	557	21.3%	398	31.0%
2000-2003	613	23.4%	261	20.3%
2004-2007	505	19.3%	218	17.0%

2008-2010	464	17.7%	195	15.2%
2011-2013	478	18.3%	212	16.5%

Table 2. Positive predictive values (PPVs) and corresponding 95% confidence intervals (CIs) of pancreatitis diagnoses registered in the Danish National Patient Registry, diagnosed at Aarhus University Hospital or Randers Regional Hospital in the period 1996-2013.

	Acute pancreatitis			Chronic pancreatitis		
	Correct	PPV	95% CI	Correct	PPV	95% CI
Overall	71/73	97.3%	90.5%-99.2%	54/65	83.1%	72.2%-90.3%
Age group						
<40 years	12/12	100.0%	75.8%-100.0%	5/7	71.4%	35.9%-91.8%
40-49 years	19/21	90.5%	71.1%-97.3%	7/9	77.8%	45.3%-93.7%
50-59 years	13/13	100.0%	77.2%-100.0%	20/25	80.0%	60.9%-91.1%
60-69 years	13/13	100.0%	77.2%-100.0%	16/17	94.1%	73.0%-99.0%
+70 years	14/14	100.0%	78.5%-100.0%	6/7	85.7%	48.7%-97.4%
Sex						
Men	33/35	94.3%	81.4%-98.4%	39/47	83.0%	70.0%-91.1%
Women	38/38	100.0%	90.8%-100.0%	15/18	83.3%	60.8%-94.2%
Hospital						
University Hospital	35/36	97.2%	85.8%-99.5%	24/28	85.7%	68.5%-94.3%

Regional Hospital	36/37	97.3%	86.2%-99.5%	30/37	81.1%	65.8%-90.5%
Calendar period						
1996-1999	6/7	85.7%	48.7%-97.4%	5/6	83.3%	43.6%-97.0%
2000-2003	11/11	100.0%	74.1%-100.0%	10/11	90.9%	62.3%-98.4%
2004-2007	18/19	94.7%	75.4%-99.1%	15/15	100.0%	79.6%-100.0%
2008-2010	17/17	100.0%	82.6%-100.0%	10/15	66.7%	41.7%-84.8%
2011-2013	19/19	100.0%	83.2%-100.0%	14/18	77.8%	54.8%-91.0%

Table 3. Self-reported tobacco smoking and alcohol abuse among patients with pancreatitis registered in the Danish National Patient Registry, diagnosed at Aarhus University Hospital or Randers Regional Hospital in the period 1996-2013.

	Acute pancreatitis		Chronic pancreatitis	
	N	%	N	%
Sampled patients	73	100.0%	65	100%
Alcohol abuse				
Never	42	57.5%	17	26.2%
Current	21	28.8%	31	47.7%
Former	4	5.5%	14	21.5%
Not reported	6	8.2%	3	4.6%
Tobacco smoking				
Never	28	38.4%	7	10.8%
Current	29	39.7%	43	66.2%
Former	7	9.6%	7	10.8%
Not reported	9	12.3%	8	12.3%