



Liver, Pancreas and Biliary Tract

## Prevalence of chronic pancreatitis: Results of a primary care physician-based population study



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### ABSTRACT

**Background:** Data on chronic pancreatitis prevalence are scanty and usually limited to hospital-based studies.

**Aim:** Investigating chronic pancreatitis prevalence in primary care.

**Methods:** Participating primary care physicians reported the prevalence of chronic pancreatitis among their registered patients, environmental factors and disease characteristics. The data were centrally reviewed and chronic pancreatitis cases defined according to M-ANNHEIM criteria for diagnosis and severity and TIGAR-O classification for etiology.

**Results:** Twenty-three primary care physicians participated in the study. According to their judgment, 51 of 36,401 patients had chronic pancreatitis. After reviewing each patient data, 11 turned out to have definite, 5 probable, 19 borderline and 16 uncertain disease. Prevalence was 30.2/100,000 for definite cases and 44.0/100,000 for definite plus probable cases. Of the 16 patients with definite/probable diagnosis, 8 were male, with mean age of 55.6 ( $\pm 16.7$ ). Four patients had alcoholic etiology, 5 post-acute/recurrent pancreatitis, 6 were deemed to be idiopathic. Four had pancreatic exocrine insufficiency, 10 were receiving pancreatic enzymes, and six had pain. Most patients had initial stage and non-severe disease.

**Conclusions:** This is the first study investigating the prevalence of chronic pancreatitis in primary care. Results suggest that the prevalence in this context is higher than in hospital-based studies, with specific features, possibly representing an earlier disease stage.

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## 1. Introduction

Chronic pancreatitis (CP) is a serious progressive disease, recently defined as a pathologic fibro-inflammatory syndrome that develops in individuals with genetic, environmental and/or other risk factors [1]. Epidemiological data on CP are scanty [2] and its incidence varies from 4 to 13/100,000 [2–4], with a progressive increase of the rate over time [5]. Although life expectancy of CP patients is shorter than that of healthy individuals [6], CP is usu-

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ally a long-standing disease and the above indicated incidence is hardly reflected by the low prevalence of CP in most studies, with rates ranging from 3 to 41/100.000 [2,5]. A formal diagnosis of CP is often difficult to be made and most of those studies are hospital-based and therefore might not represent the general population. Therefore, most likely, epidemiological studies tend to underestimate the prevalence of CP. Indeed, the autoptic prevalence of CP is much higher, ranging from 2% in controls to about 20% in patients with alcohol-related liver disease [7,8]. Interestingly, the only population-based study conducted so far on the epidemiology of CP yielded the highest prevalence of 41/100.000 [3].

There are no studies aimed at investigating the prevalence of CP in the primary care setting. However, as patients with CP present with common symptoms such as pain, weight loss and diabetes, and usually require diagnostic tests and drugs' prescription, they are likely to be followed by their primary care physicians (PCPs). The Italian National Health Service is administered on a regional basis by local health authorities (Azienda di Sanità Locale/ASL), with all citizens having a dedicated PCP who keeps track of their chronic disorders, investigations and treatments through electronic databases. According to recent studies, data on disease prevalence and outcomes obtained by healthcare administrative data collected by Local Health Authorities in five Italian regions were very similar to the estimates from clinical data collected by PCPs, suggesting the genuineness of data obtained through this approach [9].

We hypothesized that Italian PCPs might be in an ideal position to investigate the actual prevalence of CP. This is because they see not only patients with advanced disease that need frequent drug prescription for the management of pain, and exocrine or endocrine pancreatic insufficiency, but also patients in the early phases of CP who might not be seen by gastroenterologists or surgeons.

We therefore aimed at investigating the prevalence of chronic pancreatitis in the primary care setting.

## 2. Methods

### 2.1. Study protocol

One-hundred and fifty-four primary care physicians (PCPs) of the Rome area were invited to take part in three educational meetings on CP and treatment of pancreatic exocrine insufficiency (PEI) organized at S. Andrea Hospital between March 2014 and March 2015. All of them participated in at least one of the meetings. During each meeting, they were invited to participate in the present study and, after the last meeting, those who agreed were contacted by email to do so. In case of no reply, or incomplete feedback a second or third email reminder was sent. In case of no reply to any of those messages, the PCP was considered a non-participant. Each participating PCP was asked to report the area of Rome in which they worked and the total number of patients registered at their practice. Furthermore, PCPs interrogated their electronic database, prescription reports and other available registries and reported the number of patients affected by CP, filling in a specific form with details about environmental factors and disease characteristics of each patient with CP during a face to face interview whenever possible (see Supplementary material). The study lasted 9 months, between March 2015 and December 2015. The study investigation form included patients' sex and age, age at diagnosis of CP and etiology of CP. Data on morphological abnormalities and imaging procedures performed were also recorded. The presence of pain, exocrine insufficiency and diabetes, and the need of medical treatment with pancreatic enzyme replacement therapy (PERT) were also recorded. PCPs were invited to refer patients to the pancreatic disorders clinic at S. Andrea Hospital for further evaluation if needed, or in case of "uncertain" diagnosis of CP. The local

IRB approved the study and the enrolled patients gave informed consent.

### 2.2. Investigated factors and classification

The forms were reviewed by a physician (L.A.) with expertise in pancreatic disorders that, accordingly, classified CP cases. The diagnosis of CP was defined according to the M-ANNHEIM diagnostic criteria of chronic pancreatitis [10], as definite CP, probable CP or borderline CP. Etiology of CP was evaluated according to the TIGAR-O classification [11], with data on exposure to toxic agents such as alcohol and smoking, suspect of genetic or autoimmune form, previous episodes of acute pancreatitis, and obstructive causes recorded. The stages of the disease were classified according to the M-ANNHEIM clinical staging of CP classification [10] in 5 stages: 0 stage of subclinical (asymptomatic) CP, 1 stage of symptomatic CP without pancreatic insufficiency, 2 stage of partial pancreatic insufficiency, 3 stage of painful complete pancreatic insufficiency, 4 stage of secondary painless CP. The severity of the disease was classified according to the M-ANNHEIM severity index of chronic pancreatitis [10] as minor, increased, advanced, marked, exacerbated. The presence of pain, exocrine or endocrine pancreatic insufficiency and osteoporosis were also recorded, as well as the use of PERT. Regarding the morphological abnormalities that were used to define diagnosis and severity of disease, the last investigation of whom the PCP was aware was considered.

### 2.3. Statistical analysis

Results are reported as absolute number and percentages for categorical variables and for continuous variables as mean and standard deviation. We performed a *post hoc* power calculation, in order to verify if the evaluated sample population was sufficient to avoid an underestimation of prevalence. The sample size (n) is a function of the expected prevalence and precision for a given level of confidence expressed by the z statistic and is therefore directly proportional to the prevalence of the disease (P) and inversely proportional to the allowable error (d) which is a surrogate of precision. The formula used is:  $n = (z^2) P (1 - P) / d^2$  [12]. As there are no available data on the prevalence of chronic pancreatitis in Italy in the primary care setting we hypothesized that it might have been similar to that reported by Yadav et al. (41.7/100.000) in a "population-based" study. Therefore, with an allowable error equal to P/2 as typically suggested for rare diseases, and a z value of 1.96 (that corresponds to a 95% confidence with normal distribution), the obtained needed sample size  $n = 36,781$ .

## 3. Results

### 3.1. Primary care physicians participation rate

Out of the 154 PCPs, 144 (93.5%) initially agreed to be contacted. However, 121 (84%) of them eventually did not reply to the repeated invitations and were considered non-participants. Twenty-three (16%) replied and sent data on both the number of total patients registered at their practice and the prevalent cases of CP among them. There were no differences between the 23 PCPs that participated in the study and the 121 that did not, regarding sex (male 60.0% vs 62.1%;  $p = 1.00$ ) and age (mean  $53.4 \pm 12.3$  vs  $55.1 \pm 13.1$ ;  $p = 0.56$ ). There are six health assistance districts in the metropolitan area of Rome (ASL: RM1, RM2, RM3, RM4, RM5, RM6) covering a total population of about 4.290.000 inhabitants. The 23 participating PCPs were distributed among the four largest districts (5 PCPs in RM1, 7 PCPs in RM2, 6 PCPs in RM3, 5 PCPs in RM5) covering 3.511.000 inhabitants without apparent bias.

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