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Italian Chronic Pancreatitis Registry (ITARECIPE): protocol for a nationwide cohort study

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ABSTRACT

Introduction Chronic pancreatitis (CP) is a progressive inflammatory disease of the pancreas leading to permanent damage, resulting in both exocrine and endocrine insufficiency. Understanding the management of patients with CP and their outcomes is critical for improving patient care. CP is relatively rare in Italy and is characterised by various aetiologies and clinical progression requiring personalised treatment options. This registry (ITARECIPE) aims to prospectively collect and analyse data on patients with newly diagnosed CP to gain insights into its epidemiology, presentation, disease progression, and treatment outcomes.

Methods and analysis This is a multicentre, observational, non-interventional incident cohort study supported by the Italian Association for the Study of the Pancreas and endorsed by relevant Italian gastroenterological societies. ITARECIPE is the first registry in Italy focusing on newly diagnosed CP patients, leading to a comprehensive understanding of disease onset and progression. The study plans to enrol ≥300 patients annually over a minimum of 5 years. Data are recorded in a pseudo-anonymous electronic Case Report Form (eCRF) at baseline and follow-up visits, covering patient demographics, comorbidities, chronic medications, CP aetiology, pancreatic function (exocrine and endocrine), pain, complications, imaging, laboratory tests and treatments. It will track epidemiology, clinical history and treatment outcomes, potentially improving adherence to best practices and informing health policy decisions. The ITARECIPE registry will contribute significantly to the understanding of CP by providing detailed epidemiological, clinical and examinations data into disease management, which could help the development of future clinical practice and guidelines.

Ethics and dissemination The study was approved by the Ethics Committee (EC) of the promoter centre (San Raffaele Hospital, Milan, Italy; approval code 178/2022) and subsequently by the EC of each participating centre. All patients will be included after signing written informed consent and will be recorded in a pseudo-anonymous manner in a specific eCRF, in accordance with international principles and recommendations for observational studies. The ongoing results may be presented at national or international conferences and will be reported in peer-reviewed publications.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The medical literature lacks robust evidence regarding the natural history and management of chronic pancreatitis since its initial diagnosis. This disease affects the quality of life of patients, healthcare and the economic burden on the national system. Therefore, studying this condition prospectively is fundamental to evaluate its epidemiology and management across Italy.

WHAT THIS STUDY ADDS

⇒ This registry collects prospective data on chronic pancreatitis from the initial diagnosis to gather information on the epidemiology, presentation and natural history of the disease. Both academic and non-academic centres across Italy are collaborating to better understand the burden of the disease. The proposed multicentre, observational study will add more robust data on the disease incidence, presentation, progression and management of pancreatitis-related complications.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The data collected in this registry will be helpful in ascertaining the disease burden and progression, and identifying factors associated with more frequent complications. The results from this study will increase the amount of evidence on this disease with more robust data, thereby increasing the management of patients with this condition.

Trial registration number NCT05733130.

INTRODUCTION

Chronic pancreatitis (CP) is a complex chronic clinical syndrome characterised by pain and progressive organ damage, which leads to both exocrine and endocrine insufficiency.[1] Robust evidence regarding the natural history of the disease remains limited, and data are mostly based on relatively small

retrospective studies. Owing to these limitations, the actual prevalence of the disease has been reported to range from approximately 40/100 000 in studies employing verified diagnostic charts[2 3] to 100/100 000 in unverified registry studies.[4 5] This variation is due to the low positive predictive value of CP diagnosis in unverified registries.[6] Due to its relatively low prevalence and the absence of specific treatments that can stop or reverse its clinical course, CP can be considered an orphan disease for which there is a need for further research. From this perspective, prospectively maintained disease registries with data verified by physicians are particularly valuable for rare diseases, such as CP, because they help overcome the challenges inherent in studying conditions with limited prevalence. The key reasons for their utility include epidemiological insights on incidence, prevalence and disease progression; analysis of environmental exposures; and clinical presentations across the disease and help to define the typical course of the disease, including complications and long-term outcomes. Registries not only advance the understanding of rare diseases, but also pave the way for better patient outcomes through evidence-based interventions and collaborative efforts.

However, only a few registries exist for CP. In the USA, the North American Pancreatitis Study 2 (NAPS-2, 2008) includes both acute and CP.[7] In Europe, the Belgian National Registry[8] described more than 800 patients enrolled in a prospective multicentre study, and the Dutch CP Registry (CARE)[9] enrolled CP patients in a nationwide setting of over a third of all Dutch hospitals. In addition, the CARE database includes data on both chronic and acute recurrent pancreatitis, as the NAPS-2 does, limiting the effort to focus on CP patients. The Scandinavian Baltic Pancreatic Club (SBPC) database also prospectively enrolled a large cohort of patients with CP, starting enrolment in 2016,[10] and highlighted several key aspects of the disease.[11 12] However, all these studies enrolled patients at any time during their disease course when they were seen at the participating centres and not specifically at the time of diagnosis. Therefore, they only partially help in describing the natural history of CP, which could also be influenced by different environmental factors in Italy. Data on the incidence, prevalence and clinical features of CP in Italy are limited[2 13 14] and no prospective national registry exists. Therefore, our aim was to create the first nationwide multicentre Italian Registry of newly diagnosed Chronic Pancreatitis (ITARECIPE), whose main aims were to investigate the presentation and natural history of CP since its diagnosis, reporting: (a) data on Italian-specific epidemiology, the clinical presentation, aetiology and comorbidities of patients with CP and (b) the outcome of treatments and the development of complications.

METHODS AND ANALYSIS

Study design

ITARECIPE is a national multicentre, observational, non-interventional, non-experimental incident cohort study of patients with a new diagnosis of CP. The enrolled patients will follow the standard diagnostic and interventional procedures expected for their disease, both at baseline and during follow-up, according to the local clinical practice at each enrolling centre, without the need for additional procedures. The study is sponsored by the Italian Association for the Study of the Pancreas (AISP) and coordinated by a dedicated AISP Task Force (led by GC and CF and composed of MP, LA, GEMR, NdP, GB and SS) and received endorsements from the Italian Society of Gastroenterology (SIGE), Italian Association of Hospital Gastroenterology (AIGO) and the Italian Society of Digestive Endoscopy (SIED), each appointed as a representative.

Study population and eligibility

The study is expected to enrol approximately 300 patients/year, with a duration of at least 5 years, possibly extendable on amendment. The study inclusion criteria are: (a) age ≥12 years; (b) a newly established diagnosis of 'definite' or 'probable' CP according to the 'M-ANNHEIM' criteria[15]; (c) the diagnosis being made through imaging/clinical investigations within the 12 months prior to the date of enrolment; (d) willingness and capacity to provide clinical and anamnestic information on written signed informed consent. Patients can be enrolled in both the inpatient and outpatient settings.

Data collection and variables

The data of the enrolled patients from each centre will be recorded in a pseudo-anonymous manner (each patient will be identified by an ID code) at baseline and at each follow-up visit in a dedicated electronic Case Report Form (eCRF) (table 1). The AISP is responsible for the management and control of the data sent by the participating centres. Follow-up can be routinely planned 6 months after the previous or unplanned follow-up in cases requiring hospitalisation owing to new-onset symptoms. Each new episode of medical care >6 months from the previous episode will be considered a new follow-up episode.

The recorded variables included the following:

1. Patient variables: age at diagnosis, sex, region of birth and residency, body mass index (BMI) at diagnosis and body weight changes in the previous 12 months will be recorded, as well as the amount of present and/or previous smoking (pack of cigarettes per day) and/or alcohol (alcohol units for week) habits. The main medical, oncological and psychiatric comorbidities and their related chronic (at least 6 months before enrolment) pharmacological therapies will be investigated. Patients will also be specifically questioned about their familial history of acute and/or CP, pancreatic cancer and diabetes.

Table 1 Schedule for data collection

	Baseline*	Outpatients follow-up†	Hospital admission‡—inpatient setting
Enrolment: inclusion/exclusion criteria	X		
Signing informed consent	X		
e-CRF—retrospective data insertion	X		
Physical examination and clinical evaluation	X	X	X
Laboratory and instrument examinations	X	X	X
Evaluation of chronic medications	X	X	X
Complications evaluation	X		X
New clinically relevant events§		X	X

*Baseline visit is the first visit, either in an outpatient or inpatient setting.
†The time between follow-up visits will be decided according to local institutional policies.
‡Any pancreatic-related complication requiring hospital (re)admission or any admission for further examination.
§Any change in comorbidities, onset of novel diseases or pancreatic-related readmission at the hospital.
eCRF, electronic Case Report Form.

2. PC aetiology was defined according to The TIGAR-O classification[16] as toxic/metabolic, idiopathic (early or late onset), genetic (Cystic Fibrosis Transmembrane Conductance Regulator, Serine Protease 1, Serine Peptidase Inhibitor Kazal Type 1 (SPINK1), Chymotrypsin C caldecrin (CTRC), Carboxypeptidase A1 (CPA1), Maturity Onset Diabetes of the Young (MODY) or other mutations), autoimmune (type 1 (IgG4 +), type 2, not otherwise specified), recurrent (recurrent acute pancreatitis, post-necrotising AP, ischaemic AP, actinic AP) or obstructive (pancreatic divisum; cancer, duodenal cyst/ampullary lesion; post-traumatic).
3. Diagnosis of CP: the time and reason for the diagnosis of CP, either incidental or due to the presence of symptoms or signs, such as abdominal pain, steatorrhoea, weight loss, diabetes, jaundice or gastrointestinal (GI) obstruction, will be recorded. The number, severity and duration of the first and last episodes of AP, if they occurred, will also be recorded.
4. Pancreatic function: the timing of onset and the presence of pancreatic endocrine and exocrine insufficiency (PEI) will be investigated. The symptoms considered suggestive of PEI include steatorrhoea, bloating, abdominal pain and involuntary weight loss of more than 10% of the regular weight that is resolved by pancreatic enzyme replacement therapy (PERT). Faecal elastase dosage will be used to quantify PEI when data are available.[17] The use and dosage of PERT will be registered.
5. Pain: the Numeric Rating Scale (NRS, 0–10) will quantify the severity of abdominal pain. Furthermore, CP-related symptoms that result in an inability to work will be assessed.
6. Complications: will be classified as reversible or irreversible according to the M-ANNHEIM classification.
7. Stage and imaging: data on the radiological features of CP will be recorded. Morphological imaging modalities will include abdominal ultrasound (US), MRI, CT and/or endoscopic ultrasound (EUS), as performed according to the indications of the treating physician. Details about US examination will be collected as variables, including parenchymal morphology, echogenicity, presence of masses, main pancreatic duct diameter and presence of calcifications and cysts. MRI and CT scan will include more details, such as the use of contrast dye or the type of MRI (including colangiopancreatography magnetic resonance or only abdominal MRI) and more detailed features of the pancreatic parenchyma, biliary tree and MPD alterations. EUS-related variables will include the Rosemont criteria,[18] which are divided into major and minor criteria. These data, together with those of the symptoms, signs, complications and pancreatic function, will serve to define the stage of CP according to the M-ANNHEIM classification.
8. Laboratory tests: tests will be performed based on clinical practice by each treating physician: complete blood count (CBC), C reactive protein (CRP), iron, B 12 and D vitamins, folate, serum electrolytes, lipid panel, coagulative panel, electrophoresis, parathyroid hormone (PTH) and any other tests according to local follow-up policies.
9. Bone density: bone densitometry results obtained by dual-energy X-ray absorptiometry (DEXA) will be recorded when available.
10. Medical treatment for CP: any medical treatment prescribed for CP, nutritional supplements and any pain treatment will be recorded at the baseline and at each follow-up visit.
11. Endoscopic and/or surgical treatments: any endoscopic or surgical treatment performed according to the treating physician's choice will be recorded, including its indication (either pain due to duct obstruction, stricture or compression by pseudocyst or other causes, with consequent duct dilatation, jaundice due to compression or obstruction of the common bile duct, duodenal

obstruction due to enlargement of the head of the pancreas or occurrence of groove pancreatitis). The different endoscopic treatments (stenting, sphincterotomy, etc) and surgical techniques (drainage, demolition, or total pancreatectomy with or without autologous islet cell transplantation) will be recorded.

12. Disease course during follow-up: all hospitalisations occurring during follow-up, either for CP or for any other cause, will be recorded. New diagnosis of comorbidities will be recorded. Overall and disease-specific survival will be recorded.

eCRF form

The eCRF consists of a main enrolment form and follow-up visit forms, generated based on the number of follow-up visits or hospital admissions. The enrolment form is divided into six sections: (a) epidemiological data and inclusion/exclusion criteria; (b) medical history; (c) CP diagnosis, including initial symptoms, TIGAR-O classification and CP-related complications; (d) diagnostic imaging; (e) laboratory tests and (f) surgical or endoscopic treatment details.

A follow-up form is created each time a patient visits the hospital for planned outpatient follow-up or not planned inpatient admission due to an acute event. This form condenses multiple sections, including: (a) general evaluation (new CP-related factors, endocrine/exocrine insufficiency and nutritional status); (b) imaging, laboratory tests and interventional therapies and (c) new clinical conditions (hospital admissions, comorbidities, updated M-ANNHEIM index and date of death, if applicable). A sample eCRF is provided in online supplemental material.

Study endpoints

The main purpose of this registry is to collect prospective data on CP from the initial diagnosis to gather information on the presentation and natural history of the disease in terms of its symptoms and signs; epidemiology; disease progression; need for medical, endoscopic or surgical therapy; the risk of pancreatic exocrine and endocrine insufficiency; and the risk of developing pancreatic and extra-pancreatic complications (including cancer) and death.

Statistical methods

The study does not have a predefined sample and will enrol all the patients who are seen at the participating centres during its duration. However, given the number of centres that are expected to take part (20–40) and the known incidence of the disease in Italy, it is estimated that at least 1500 patients will be included in the registry in the first 5 years.[8] Given the observational nature of the study, no formal power calculations were performed. The planned timeline includes a descriptive analysis after the first year of data collection and subsequently every 6 months, alongside the following statistical analyses: distributions of enrolled cases by region of origin, sex, age, pathology characteristics, treatment, and follow-up.

In addition, after at least 12 months of enrolment in a minimum of 40 centres in Italy and at least one centre per geographical region of Italy, an attempt will be made to evaluate the incidence of CP. To this end, we will define the catchment area for each centre and estimate the total population at risk in those regions. We will collect data on new incident cases of CP diagnosed across the centres over 12 months. If 100 new cases are reported and the combined population at risk in the catchment areas is 1 million, the incidence rate is (100 new cases/1 000 000 population)×100 000.

Continuous variables will be expressed as means with SD or median with IQR based on the normality of their distribution, and categorical variables as percentages and will be compared using the χ^2 test or Fisher's exact test based on the sample sizes and conditions for each application of the test. Variables will be compared in univariate analyses using the Mann-Whitney U test or Student's t-test, depending on their respective applicability conditions. A logistic regression model will be used for association with the outcomes. The survival function will be estimated by Kaplan-Meier curves, and the Cox proportional hazard model will be used as a regression model to explore associations with predictor variables. Differences will be considered statistically significant if the p value will be <0.05.

As for the management of missing variables, the inherently observational methodology does not impose a specific clinical approach, and some key information may be absent from the registry due to unavailability, patient refusal or documentation errors. However, some specific fields are designated as 'mandatory' or 'required' to ensure the collection of essential information (see eCRF form in online supplemental material for more details). Also, to enhance data completeness, the study coordinators will regularly issue queries to sites, prompting them to input missing data or correct inaccuracies. Finally, for data that remain unavailable at the time of analysis, cases with missing mandatory variables will be excluded. For non-mandatory variables, single imputation will be applied, using a regression model to predict missing values. Any potential bias introduced by the imputation method will be taken into account when interpreting confidence intervals or p-values.

Ethics and dissemination

The study was approved in September 2022 by the coordinating centre Ethics Committee (EC) of San Raffaele Hospital in Milan (approval code 178/2022) and subsequently by the EC of each centre. The enrolment started at the promoter centre (San Raffaele Hospital) at the end of 2022. ITARECIPE is registered on Clinical Trial.gov (NCT05733130) and will be conducted according to the principles and the recommendations of the 2013 Declaration of

Figure 1 Geographical distributions of actively recruiting Italian centres.

Helsinki and under the guide of Agency for Healthcare Research and Quality (AHRQ): Registries for Evaluating Patient Outcomes: A User's Guide.[19] Data will be collected and included in the eCRF only if the patients provide written informed consent. Figure 1 shows the geographical distribution of the centres approved by the EC and actively recruiting. The ongoing results may be presented at national or international conferences over the years and will be reported in peer-reviewed publications.

DISCUSSION

CP is a relatively rare disease in Italy[2 13 20] and is characterised by a heterogeneous aetiology, clinical course and treatments, for which there is a strong need for a tailored, personalised patient pathway.[21] The use of observational methods, including prospective long-term patient registries, is fundamental in building broad and comprehensive knowledge of heterogeneous diseases such as CP.[19] Although several registries for CP have been implemented in other countries, none of them enrolled

only patients with a new diagnosis, from the time of presentation, with a prospective design, in order to investigate the natural history of the disease. ITARECIPE will be the first study of this kind, and the first CP registry in Italy. Moreover, similarly to the Indian registry for CP (EPICAP-India),[22] ITARECIPE aims at analysing the epidemiology of the disease, in terms of incidence and prevalence of CP. Indeed, while most CP registries enrolled both incident and prevalent cases, including patients who experienced disease onset several years before enrolment, ITARECIPE will only enrol newly diagnosed CP patients to ensure a more robust description of the disease features from the beginning and to track diagnostic patterns to identify gaps or delays in early disease recognition. It is expected that this approach will allow the depiction of the role of environmental factors, such as smoking and alcohol use, during the disease. We hypothesise that the incidence and prevalence of CP were underestimated in previous studies in Italy.[2 12 13] We also expect to observe a higher proportion of cases in regions such as Lombardy, in the north of Italy, where a regional hub-spoke system of 'Pancreas Centres' for the care of pancreatic cancer has been established, possibly raising the awareness of physicians on pancreatic disorders.[23] Additionally, such a registry will facilitate phenotyping and sub-classification of CP, which is essential for precision medicine approaches and help optimisation the diagnosis and management of the condition. In this view, when compared with older studies, we expect to observe a lower rate of alcoholic CP and a higher rate of genetic aetiology, with also a higher rate of 'painless' disease.

ITARECIPE will also keep track of clinical history, including follow-up, and will assess treatment outcomes to establish best practices for medical, endoscopic or surgical management. This may improve adherence to the best practices. As an example, current evidence suggests that drainage surgery is superior to an endoscopic approach in patients with painful CP and dilated pancreatic duct.[24–26] Nonetheless, endoscopic therapy is frequently the first intervention in many centres because it is less invasive and does not preclude subsequent surgery, as well as moderate-to-severe pain that does not respond to medicinal therapy. More widely, adherence to the best evidence and guidelines is often low in the care of patients with CP. We expect to be able to highlight the lack of adherence to guidelines, especially regarding the treatment options, and to possibly promote education in order to improve patient care. In 2016, the United European Gastroenterology evidence-based guidelines for the diagnosis and therapy of CP (HaPanEU) were released,[27] and the Dutch CARE registry permitted the identification of a suboptimal adherence rate of 53% among patients with CP using recommendations graded as strong and high-quality evidence as a reference standard. This low adherence was not explained by sex, aetiology, hospital setting and age, suggesting and supporting the need to implement national programmes or registries for physicians to improve the quality of care for patients with CP. One of the areas that is more often overlooked in common clinical practice is nutritional status and its complications, such as the impact on the musculoskeletal system, in patients with CP.[28–31] This will also be assessed in the ITARECIPE.

ITARECIPE will also serve as a potential resource for patient recruitment in clinical trials, which is particularly challenging for rare diseases and might produce data that help quantify the burden of the disease, including healthcare costs, quality of life and societal impacts, ultimately informing health policy decisions in Italy. A limitation of this protocol is the relatively low rate of specialised 'Pancreas Centres' in Italy, and their different distribution across the country.[32] This could have an impact on the analysis of data, which will be adjusted accordingly with centres' volume and expertise as a covariate. Also, as with any registry-based study, ITARECIPE is inherently observational, meaning it does not impose specific patient visit schedules, mandate particular diagnostic or laboratory tests, or enforce specific follow-up intervals. Consequently, some information may be absent from the registry due to unavailability, patient refusal or documentation errors. Nonetheless, the registry primarily captures data reflecting standard clinical practice, increasing the likelihood of their inclusion. At any rate, a specific policy for the management of missing data is detailed in the methods section.

Finally, the ITARECIPE board is open to multicentre and international collaborations, enhancing sample size and diversity and allowing a comparison of findings in different countries and ethnicities. The ITARECIPE registry will contribute to understanding CP by providing detailed epidemiological, clinical and radiological data for disease management, which could help the development of future clinical practice and guidelines.

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Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study.

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