The Voice of the Patient With Exocrine Pancreatic Insufficiency Secondary to Chronic Pancreatitis: Preliminary Findings From a Patient-Driven Registry

C0007

Jodie A. Barkin, MD[1]; Yasmin G. Hernandez-Barco, MD[2]; Samer Al-Kaade, MD[3]; Rahul Pannala, MD[4]; Janine Twal, PharmD[5]; Valerie J. Powell, MS[6]; David C. Whitcomb, MD, PhD[7]

[1]University of Miami Miller School of Medicine, Miami, FL, USA; [2]Massachusetts General Hospital, Boston, MA, USA; [3]Advanced Endoscopy, Mercy Clinic Gastroenterology, St. Louis, MO, USA; [4]Mayo Clinic Arizona, Phoenix, AZ, USA; [5]Aimmune Therapeutics, a Nestlé Health Science company, Brisbane, CA, USA; [6]CorEvitas, LLC, Waltham, MA, USA; [7]University of Pittsburgh, UPMC and Ariel Precision Medicine, Pittsburgh, PA, USA

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INTRODUCTION

- Exocrine pancreatic insufficiency (EPI) is caused by reduced or inappropriate pancreatic enzyme secretion or activity, which may manifest as signs or symptoms including steatorrhea, weight loss, and micronutrients malabsorption or maldigestion[1]
- EPI remains underdiagnosed and undertreated despite its impact on quality of life (QoL) and increased morbidity/mortality[2]
- Chronic pancreatitis (CP) is the most common disease of the pancreas associated with EPI[1]
- The North American Pancreatitis Study 2 explored the natural history (including exocrine insufficiency) of recurrent acute pancreatitis (RAP) and CP[3]; however, more data are needed on this subgroup
- To better understand EPI, its impact on QoL and healthcare resources, and treatment effects, an innovative dual approach using a patient online community and a patient-driven traditional registry was employed to collect data from patients and their gastroenterologists on real-world experiences with EPI and pancreatic enzyme replacement therapy (PERT)

OBJECTIVE

- To report preliminary findings from a prospective registry of individuals living with EPI due to CP

METHODS

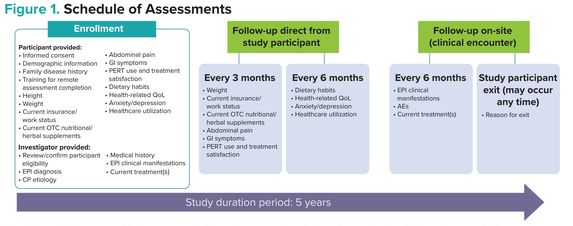
- This is a prospective, noninterventional study in the United States with a planned enrollment of 400 patients, spanning ~5 years
  - Recruitment to occur over 24 months
  - Inclusion of ~20 gastroenterology practices
- Assessments are collected at prespecified intervals (Figure 1)

Eligibility Criteria

Inclusion Criteria:
- Adults with suspected/confirmed EPI by a healthcare provider
- Receiving PERT (either prior to enrollment or newly prescribed at enrollment)
- Diagnosed with CP/RAP at enrollment

Exclusion Criteria:
- Patients with history of cystic fibrosis, fibrosing colonopathy, or pancreatic cancer/malignancies

Figure 1. Schedule of Assessments



Abbreviations: AE, adverse event; CP, chronic pancreatitis; EPI, exocrine pancreatic insufficiency; GI, gastrointestinal; OTC, over-the-counter; PERT, pancreatic enzyme replacement therapy; QoL, quality of life.

Statistical Analysis

- All data to date were summarized descriptively
- Multivariate modeling will be used to analyze effects of medical history, comorbidities, and treatments on EPI history/progression, QoL, and healthcare resource use in order to understand the impact of clinical practices and EPI clinical course

RESULTS

Patient Demographics and Characteristics

- As of February 22, 2022, a total of 35 patients are enrolled (Table 1)
- 13 patients reported having experienced unintentional weight loss
- 2 patients had a familial history of chronic pancreatitis

Table 1. Patient Demographics and Characteristics

Characteristic	Total N=35
Patient demographics[a]	
Age (years), median (range)	62 (31–81)
Sex, n (%)	
Male	16 (45.7)
Female	14 (40.0)
Race, n (%)	
White	23 (65.7)
Black or African American	3 (8.6)
Asian	2 (5.7)
Other	2 (5.7)
Ethnicity, n (%)	
Hispanic or Latino	6 (17.1)
Not Hispanic or Latino	24 (68.6)
Weight at enrollment (lbs)	
n	30
Mean (SD)	179.5 (33.5)
Median	185.0
Min, Max	109, 251

[a]Data were unavailable for 5 patients at the time of data analysis.
Abbreviations: Max, maximum; Min, minimum, SD, standard deviation.

Disease Characteristics at Baseline

- Alcohol (susceptibility/progression) and diabetes mellitus were common etiologies (Table 2)

Table 2. Disease Characteristics at Baseline

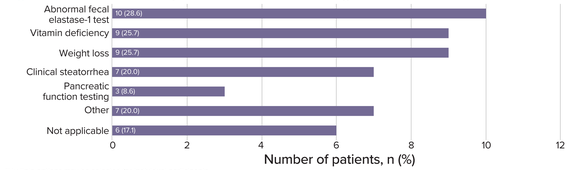
Chronic Pancreatitis Etiology[a,b], n (%)	Total N=35
Toxic-metabolic	
Alcohol (susceptibility/progression)	13 (37.1)
Tobacco smoking	7 (20.0)
Hyperlipidemia (fasting >300 mg/dL, nonfasting >500 mg/dL)	5 (14.3)
Medications	3 (8.6)
Toxins, other	3 (8.6)
Toxins, other, not otherwise specified	3 (8.6)
Hypercalcemia (total calcium levels >12.0 mg/dL or 3 mmol/L)	2 (5.7)
Toxins, chronic kidney disease (stage 5, end-stage renal disease)	1 (2.9)
Not applicable	16 (45.7)
Metabolic, other	
Diabetes mellitus	12 (34.3)
Not applicable	23 (65.7)
Idiopathic	
Late (>35 years of age)	12 (34.3)
Early (<35 years of age)	2 (5.7)
Not applicable	21 (60.0)

[a]Selected chronic pancreatic etiology; other categories not shown include genetic, autoimmune, recurrent and severe acute pancreatitis, obstructive, and other.
[b]Multiple options may be selected for individual participants.

EPI Diagnosis

- Abnormal fecal elastase-1 test, vitamin deficiency, and weight loss were frequently used evidence for EPI diagnosis (Figure 2)

Figure 2. Evidence of Suspected/Confirmed EPI Diagnosis[a]

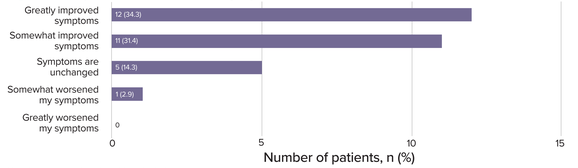


[a]Multiple options may be selected for individual participants.
Abbreviation: EPI, exocrine pancreatic insufficiency.

PERT Use

- 25 (71.4%) patients reported taking their PERT or enzymes every day
  - 11 patients reported taking PERT with meals only
  - 15 patients reported taking PERT with meals and snacks
- Median number of pills of PERT taken every day was 6
- Patients generally reported PERT greatly or somewhat improved symptoms (Figure 3)

Figure 3. Impact of PERT Use on Symptoms[a]

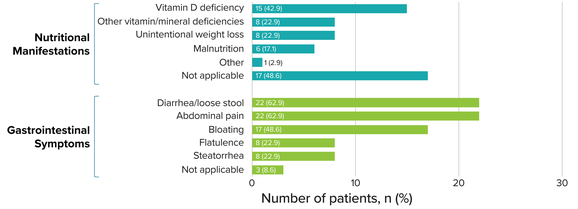


[a]Multiple options may be selected for individual participants.
Abbreviation: PERT, pancreatic enzyme replacement therapy.

EPI Clinical Manifestations

- EPI presented in a variety of ways (Figure 4)
- Steatorrhea was present some of the time in 14 patients; 12 never had steatorrhea
- Over the past 3 months, 10 patients reported ER visits; 7 needed hospitalization

Figure 4. Clinical Manifestations of EPI[a]



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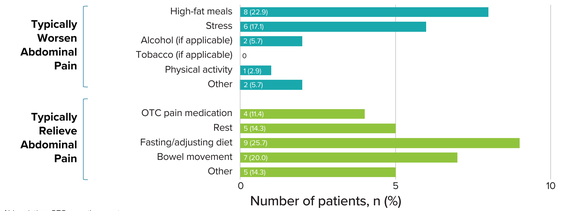
Abdominal Pain at Visit 1

- 11 patients experienced episodes of mild/moderate pain
  - These patients had a median of 3 episodes of abdominal pain in the past month
  - 8 patients reported that the episodes lasted a few hours
- 11 patients reported abdominal pain lasting longer than 6 months
- Abdominal pain was severe enough to prompt medical attention for 7 patients
- 4 patients had recent hospitalizations because of abdominal pain and 2 were hospitalized for a week
- Several aggravating and remitting factors that affected abdominal pain were noted (Figure 5)

Figure 5. Factors That Affected Abdominal Pain



Abbreviation: OTC, over-the-counter.

CONCLUSIONS

Enrolled patients with EPI are diverse in terms of demographics, etiologies, and clinical presentations

Initial findings include heterogeneous diagnostic methodologies, substantial but not overwhelming presence of steatorrhea, and improvement of symptoms with PERT in most patients

Early experience confirms feasibility of this data collection modality in those with CP

Enrollment into the registry and data collection are ongoing

Future analyses will help clarify areas of unmet needs in EPI management, patient experience, and patient/physician factors that may affect treatment success

References

1. Capurso G, et al. *Clin Exp Gastroenterol.* 2019;12:129-139. **2.** Diéguez-Castillo C, et al. *Medicina (Kaunas).* 2020;56(10):523. **3.** Whitcomb DC, et al. *Pancreatology.* 2008;8(4-5):520-531.

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PACT-CP
PAtient-CenTric Chronic Pancreatitis Registry

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