Baseline Demographics and Clinical Characteristics of Chronic Thromboembolic Pulmonary Hypertension Patients in the US Medicare Population

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BACKGROUND

- Chronic thromboembolic pulmonary hypertension (CTEPH) is a serious condition characterized by an increase in pulmonary vascular resistance which can lead to right ventricular failure and death.[1]
- CTEPH can be managed surgically with pulmonary endarterectomy (PEA) and balloon pulmonary angioplasty (BPA).[2,3]
- Studies have shown that the 3-year survival rate for untreated CTEPH can be as low as 10%, depending on the mean pulmonary artery pressure levels. However, with the advent of modern treatment, the overall 3-year survival rate may reach 70% for medically inoperable CTEPH patients and 93% for operable CTEPH patients.[4,5,6]

OBJECTIVES

Examine baseline demographics and clinical characteristics of CTEPH patients identified in the US Medicare population.

METHODS

This was a retrospective database study using the US Medicare database from January 1, 2013 through December 31, 2016.

Study Sample

Patients were included in the procedure CTEPH (P-CTEPH) population if they satisfied all of the following criteria:

- ≥1 claim for PEA or BPA procedures during the study period—the first procedure claim date was defined as the procedure date;
- ≥1 pharmacy claim for evidence-based CTEPH pharmacotherapy (riociguat or macitentan) during the identification period (01JAN2014-31DEC2016). The first claim date for the evidence-based CTEPH pharmacotherapy during the identification period was defined as the index date.
- an additional refill of CTEPH evidence-based pharmacotherapy(ies); and
- continuous health plan enrollment with medical and pharmacy benefits between the procedure date and the index date for 12 months pre-index date (baseline period) and ≥1 month post-index date—patient data were assessed until health plan disenrollment, death, or the end of the study period.

Patients were included in the non-procedure CTEPH (NP-CTEPH) population if they satisfied all of the following criteria:

- ≥3 months of continuous riociguat use—the first riociguat claim date during the identification period was designated as the CTEPH pharmacotherapy initiation date, the first riociguat claim date was defined as the index date for patients prescribed only riociguat (monotherapy), and the first claim date for macitentan was defined as the index date for patients prescribed riociguat and macitentan (combination therapy) during the identification period;
- ≥2 diagnosis claims for pulmonary hypertension and ≥1 diagnosis for pulmonary embolism (PE) on or before the CTEPH pharmacotherapy initiation date; or
- continuous health plan enrollment with medical and pharmacy benefits for 12 months pre-index date (baseline period) until ≥1 month post-index date—patient data were assessed until health plan disenrollment, death, or the end of the study period.

Two cohorts were constructed:

- **P-CTEPH Cohort:** Patients who had ≥1 BPA or PEA procedure during the study period and were prescribed CTEPH evidence-based pharmacotherapy during the identification period
- **NP-CTEPH Cohort:** Patients who do not have a PEA or BPA procedure during the study period, but had diagnosis for PE and PH and were prescribed riociguat with or without macitentan during the identification period

Baseline and Outcome Variables

- **Baseline Demographic and Clinical Characteristics:** Age, sex, geographic region, Charlson comorbidity index score, individual comorbidities, baseline pharmacotherapy, the rate of PEA/BPA procedures, and the time to PEA/BPA procedures.

Statistical Analysis

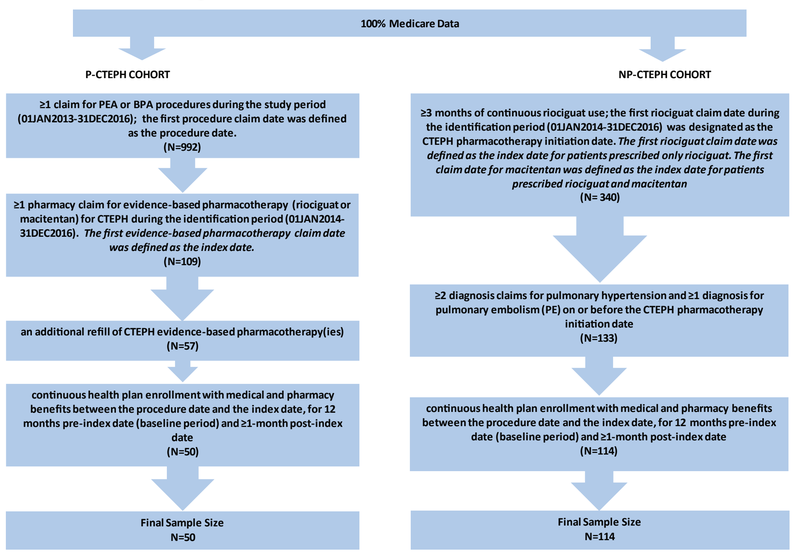
Descriptive Analysis

- All baseline and outcome variables were analyzed descriptively. Mean, standard deviation, median and range were provided for continuous variables. Numbers and percentages were provided for binary or categorical variables.

RESULTS

After applying the inclusion and exclusion criteria, 50 patients were identified for the P-CTEPH population and 114 patients were identified for the NP-CTEPH population (Figure 1).

Figure 1. Flow Chart for Patient Selection Criteria



BPA: balloon pulmonary angioplasty; CTEPH: chronic thromboembolic pulmonary hypertension; NP: non-procedure; P: procedure; PE: pulmonary embolism; PEA: pulmonary endarterectomy

RESULTS (cont'd)

Baseline Results for P-CTEPH and NP-CTEPH Cohorts

Demographic and Clinical Characteristics

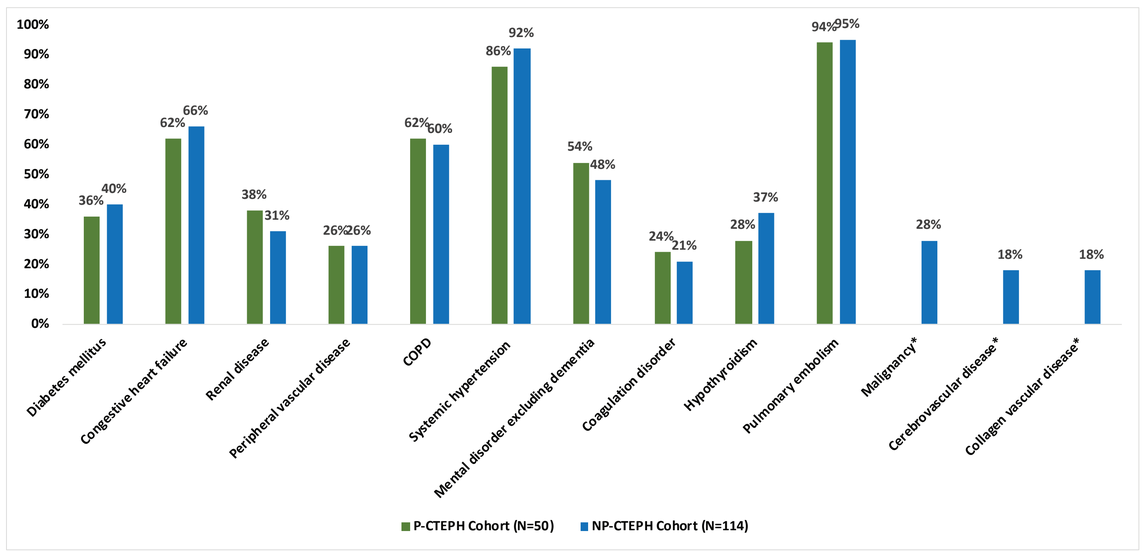
Table 1. Baseline Characteristics for P-CTEPH and NP-CTEPH Patients During 12-month Baseline Period

Demographic Characteristics	P-CTEPH Cohort (N=50)		NP-CTEPH Cohort (N=114)	
	N/Mean	%/SD	N/Mean	%/SD
Mean age (years)	65.2	11.6	71.3	10.8
Median age (Range)	68	(31-79)	73	(37-91)
Age group				
≥65	34	68%	91	80%
Sex				
Female	25	50%	72	63%
Race				
White	38	76%	86	75%
Non-White	12	24%	28	25%
US Geographic Region				
Northeast/West	21	42%	47	41%
North Central	16	32%	27	24%
South	13	26%	40	35%
Comorbidities				
Charlson Comorbidity Index Score	4.4	2.8	4.7	2.7
<2	17	34%	33	29%
3-4	12	24%	20	18%
>4	21	42%	71	62%

CTEPH: chronic thromboembolic pulmonary hypertension; NP: non-procedurel P: procedure; SD: standard deviation

- NP-CTEPH patients were required to have ≥1 PE diagnosis on or before the index date. Of these patients, nearly 95% had ≥1 PE diagnosis on or 12 months before the index date (Figure 2). The remaining 5% of NP-CTEPH patients had ≥1 PE diagnosis claim before the 12-month baseline period.

Figure 2. Baseline Individual Comorbidities for P-CTEPH and NP-CTEPH Patients



*Only outcomes for groups of >11 patients are presented due to Health Insurance Portability and Accountability Act (HIPAA) guidelines.
COPD: chronic obstructive pulmonary disease; CTEPH: chronic thromboembolic pulmonary hypertension; NP: non-procedure; P: procedure

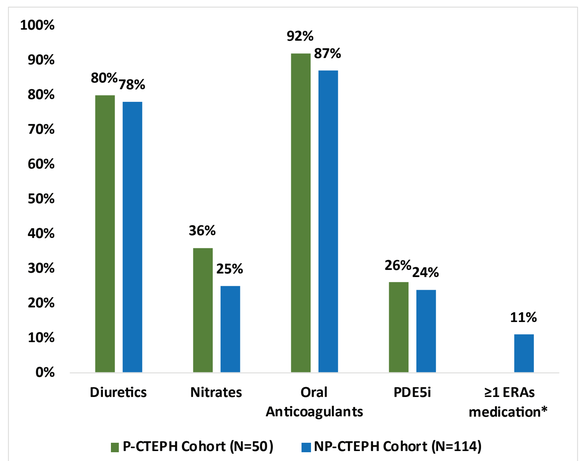
- Most of the patients in the P-CTEPH cohort (72%) had their BPA/PEA procedure after their first CTEPH pharmacotherapy treatment. The median time between the index date and PEA and BPA was 184 and 300 days, respectively (Table 2).

Table 2. The Rate and Time to BPA and PEA Procedure Among P-CTEPH Patients

BPA and PEA Procedures*	P-CTEPH Cohort (N=50)	
	N	%
# patients with PEA before first CTEPH pharmacotherapy treatment	12	24%
# patients with PEA after first CTEPH pharmacotherapy treatment	32	64%
# patients with PEA/BPA after first CTEPH pharmacotherapy treatment	36	72%
BPA and PEA Procedures*	**Mean/ median**	**SD/(Range)**
Mean time from PEA to index date (days)	255	169.5
Median time from PEA to index date (days)	184	(64-624)
Mean time from BPA to index date (days)	371	301.6
Median time from BPA to index date (days)	300	(76-728)

*Only outcomes for groups of >11 patients are presented due to HIPAA guidelines.
BPA: balloon pulmonary angioplasty; CTEPH: chronic thromboembolic pulmonary hypertension; P: procedure; PEA: pulmonary endarterectomy; SD: standard deviation

Figure 3. Baseline Pharmacotherapy for P-CTEPH and NP-CTEPH Patients



*Only outcomes for groups of >11 patients are presented due to HIPAA guidelines.
CTEPH: chronic thromboembolic pulmonary hypertension; ERA: endothelial receptor antagonists; NP: non-procedure; P: procedure; PDE5i: phosphodiesterase type 5 inhibitor

LIMITATIONS

- Claims data are collected for payment and may have certain inherent research limitations.
- No specific International Classification of Diseases, 9th/10th Revision, Clinical Modification (ICD-9/10-CM) codes for CTEPH were available at the time of the study.
- The presence of a diagnosis code on a medical claim may not signify a positive presence of the disease; the diagnosis code might have been incorrectly inputted or included as a rule-out criterion rather than an actual disease.

CONCLUSIONS

- In a real-world database, CTEPH patients were identified using 2 distinct selection criteria.
- Overall, the NP-CTEPH cohort was older, had a higher frequency of comorbidities, and higher CCI compared to the P-CTEPH cohort.

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