Medical Chart Abstraction to Confirm Diagnosis and WHO Functional Class of Pulmonary Arterial Hypertension in Patients Identified via a U.S. Retrospective Claims Database

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Background

Pulmonary arterial hypertension (PAH) is a rare disease in which patients experience increased pulmonary vascular resistance (PVR) and pulmonary arterial pressure that result in remodeling of the pulmonary vasculature and may lead to right heart failure and premature death.[1] The prevalence is 10.6 cases per million people in the US.[2] The incidence of PAH in the US is 2.0 cases per million people annually.[2] Retrospective database studies of PAH using US payer claims data have limitations due to lack of specific ICD-9 codes for PAH and ability to identify patient severity. Previous retrospective claims studies used an algorithm which includes patients with non-specific pulmonary hypertension (PH) ICD-9 codes, along with a claim for an advanced PAH drug therapy.[3,4,5] This study attempts to validate the diagnosis algorithm and identify patient disease severity through linkage to data abstracted from medical charts.

Objective

To evaluate validity of a retrospective review of payer database along with chart abstraction for confirmation of PAH diagnosis and identification of World Health Organization Functional Class (FC).

Methods

- **Study Design:** The study was a retrospective mixed methods study using health plan claims data and data abstracted from medical charts for observations of PAH diagnosis, WHO functional class, clinical and therapeutic information , and medication use
- **Data Source:** Humana Research Database (Humana, Louisville, KY, USA) which includes data from geographically dispersed US commercial and Medicare health plans, providing coverage for approximately 16 million members. The data set consists of integrated medical claims, pharmacy claims, laboratory claims and eligibility files. Additionally, patient medical charts were abstracted.
- **Inclusion and Exclusion Criteria**:
  - Enrolled Medicare Advantage member at index (first claim for a FDA approved treatment for PAH during study time period)
  - Pharmacy or medical claim during the identification period for an FDA approved treatment for PAH: oral endothelin-receptor agonist (ERA) , oral phospodiesterase type 5 (PDE-5) or an inhaled prostacyclin
  - A medical claim with a diagnosis of Primary Pulmonary Hypertension (416.0), Other Pulmonary heart diseases (416.8), or Chronic pulmonary heart disease, unspecified (416.9)
- **Outcomes:**
  - Presence of PAH diagnosis
  - WHO Functional Class
  - Clinical and diagnostic measures
- **Statistical Analyses:** Descriptive statistics
- **Study Time Period:** 1/1/2007-9/30/2013
- **Abstraction:** Sub-sample of 110 subjects were selected randomly from 10 sites for this pilot study. The 10 sites were chosen based on a selection of zip codes from providers, who were identified via medical and pharmacy claims to have patients meeting the study inclusion and exclusion criteria. Provider specialty was also considered to avoid over/under representation of any particular specialty in the study sample.
  - A PAH specific abstraction form was developed for use in this study
  - A chart abstracting vendor contacted providers to obtain charts and abstract data to a case report form based on the desired study outcomes
  - In addition to presence of a PAH diagnosis and WHO functional class, clinical signs , symptoms and diagnosis were collected to support documentation of diagnoses and/or functional class

Results

Table 1. Chart Abstraction Process Summary

	Total	Percent
Goal	50	
Chart Request Sent	110	
Charts Abstracted	**43**	**39.1%**
Unobtainable Total	67	60.9%
Unobtainable Reasons		
Cannot Locate Provider	18	16.4%
No Record of Patient	16	14.5%
No Record of Patient in timeframe requested	8	7.3%
Provider refuses to participate	1	0.9%
Chart lost/destroyed/archived	6	5.45%
Contacted multiple times, no response	4	3.6%
Prepayment denied	2	1.8%
Chart not received by the end of study period	1	0.9%

Table 2. PAH Diagnosis and Classification

	N	Percent
PAH Diagnosis on Chart	**42**	**97.7%**
WHO Functional Class Present	**4**	**9.3%**
WHO Functional Class 1	1	2.3%
WHO Functional Class 3	3	7.0%

Summary of Findings

- Thirty-nine percent (N=43) of requested charts were obtained and abstracted
- The most frequent reason for non-attainment was “Unable to locate provider or patient”
- The majority (98%) of patients had a PAH diagnosis documented on the chart
- WHO Functional Class was not consistently documented in the charts obtained. Less than 10% had a documented functional class assignment on chart
- Clinical testing, signs and symptoms, were not consistently documented to support WHO Functional Class assignment

Table 3. Chart Abstraction Clinical Findings

	N	Percent
Diagnostic Testing		
Acute Vasodilator testing Performed	2	4.7%
Right heart catheterization performed	1	2.3%
Signs and Symptoms		
Dyspnea	28	65.1%
Edema	18	41.9%
Fatigue	12	27.9%
Right Heart Failure	12	27.9%
Chest Pain	5	11.6%
Raynaud's Symptoms	5	11.6%
Dizziness	2	4.7%
Exertional lightheadedness	2	4.7%
Limitations on physical activities	2	4.7%
Bloating	1	2.3%
Comfortable at Rest	1	2.3%
Near/Pre Syncope	1	2.3%
Syncope	1	2.3%
Pulmonary ejection click	1	2.3%
Accentuated pulmonic component (P2 of S2)	1	2.3%
Tricuspid murmur	1	2.3%
Clinical Testing		
Mean Pulmonary Artery Pressure (mPAP)	13	30.2%
Pulmonary Capillary Wedge Pressure (PCWP)	4	9.3%
Cardiac Output	2	4.7%
Pulmonary Vascular Resistance (PVR)	2	4.7%
Right Atrial Pressure (RAP)	2	4.7%
Left Ventricular Pressure (LVP)	1	2.3%
Transpulmonary Pressure Gradient (TPB)	1	2.3%
Medications*		
Sidenafil	29	67.4%
Bosentan	12	27.9%
Treprostinil (IV,SQ)	9	20.9%
Tadalafil	5	11.6%
Ambrisentan, epoprostenol, Iloprost, and inhaled Treprostinil	0	0%

Only U.S. FDA Approved medications for the treatment of PAH at the time of this study were included.

Conclusions

- The frequently used diagnostic algorithm[3,4,5] correctly identified patients with a documented PAH diagnosis in 98% of cases, offering researchers a valid method of identifying cases of PAH in payer claims data
- WHO Functional Classification was consistently not documented in the medical charts
- Numerous different types of medical record systems (paper, hybrid, electronic, etc.) made consistent retrieval challenging
- Patients have charts at multiple providers with no one chart having a complete documentation of the diagnosis, progression and disease management
- A multi-provider approach to obtaining medical data for PAH research is needed to provide complete diagnostic and assessment data for the patient
- Effective chart abstraction strategies should include verification of provider, practice and provider location
- Other sources of severity information may prove useful in future research, i.e.: specialty pharmacy records, prior authorization forms, etc.

Limitations

- Record retention practices and differing institutional policies regarding consent in chart abstraction studies limited response rate
- Provider and patient turnover at sites limited the ability to locate charts
- Provider identifiers were not used exclusively by individual practitioners, making it difficult to target a specific provider

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