

Clinical Burden and Practice Patterns in Patients With Chronic Hypoparathyroidism in the United States (US):

A Claims Data Analysis Using Diagnosis-Based Criteria

Dolly Sharma, PhD¹, Kathleen L. Deering, Pharm D¹, Patrick Loustau, MS, MA², Michael D. Culler, PhD², Soraya Allas, MD, PhD³, Blandine Weiss, Pharm D, MS², Deborah M. Mitchell, MD⁴, Danette Astolfi, MBA⁵, Michael Mannstadt, MD⁴

¹EPI-Q Inc., Oak Brook, IL, USA, ²Amolyt Pharma, Cambridge, MA, USA, ³Amolyt Pharma, Ecully, France, ⁴Endocrine Unit, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA, ⁵Hypoparathyroidism Association Representative, Wescosville, PA, USA.

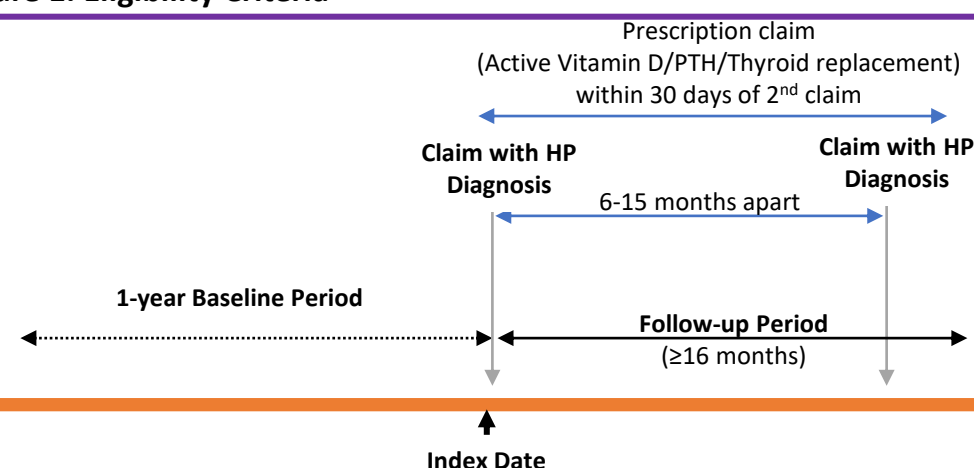
INTRODUCTION

- Chronic hypoparathyroidism (cHP) is a rare disorder, characterized by low serum calcium and low endogenous parathyroid hormone (PTH).
- Few studies to date have characterized patients with cHP.
- One study in the US has utilized claims data to assess the incidence and prevalence of cHP, however, patient characteristics and outcomes of cHP were not assessed (Powers et al., JBMR 2013).
- Study Objective:** To assess the clinical burden and practice patterns in patients with cHP identified using diagnosis-based criteria in a US claims database.

METHODS

- Study Design:** Non-interventional retrospective claims data analysis
- Data Source:** HealthVerity closed payer claim medical and pharmacy database (Private Source 20) with 130 million covered lives.
- Study Period:** October 1, 2014 - December 31, 2019
- Study Population:** Patients identified with cHP using a diagnosis-based approach. Eligibility criteria (Figure 1) were adapted from a study by Powers et al:
 - Presence of ≥2 claims with diagnosis of HP 6-15 months apart (International Classification of Diseases, ICD 9/10 codes: E20.0, E20.8, E20.9, 252.1) and a prescription claim for either active vitamin D, calcium, PTH, or thyroid replacement therapy between the first qualifying HP claim and within 30 days of the second HP claim
 - Index date: Date of the first of two qualifying HP diagnosis claims
 - Patients continuously enrolled for a year before the index date and a minimum of 16 months after the index date

Figure 1. Eligibility Criteria

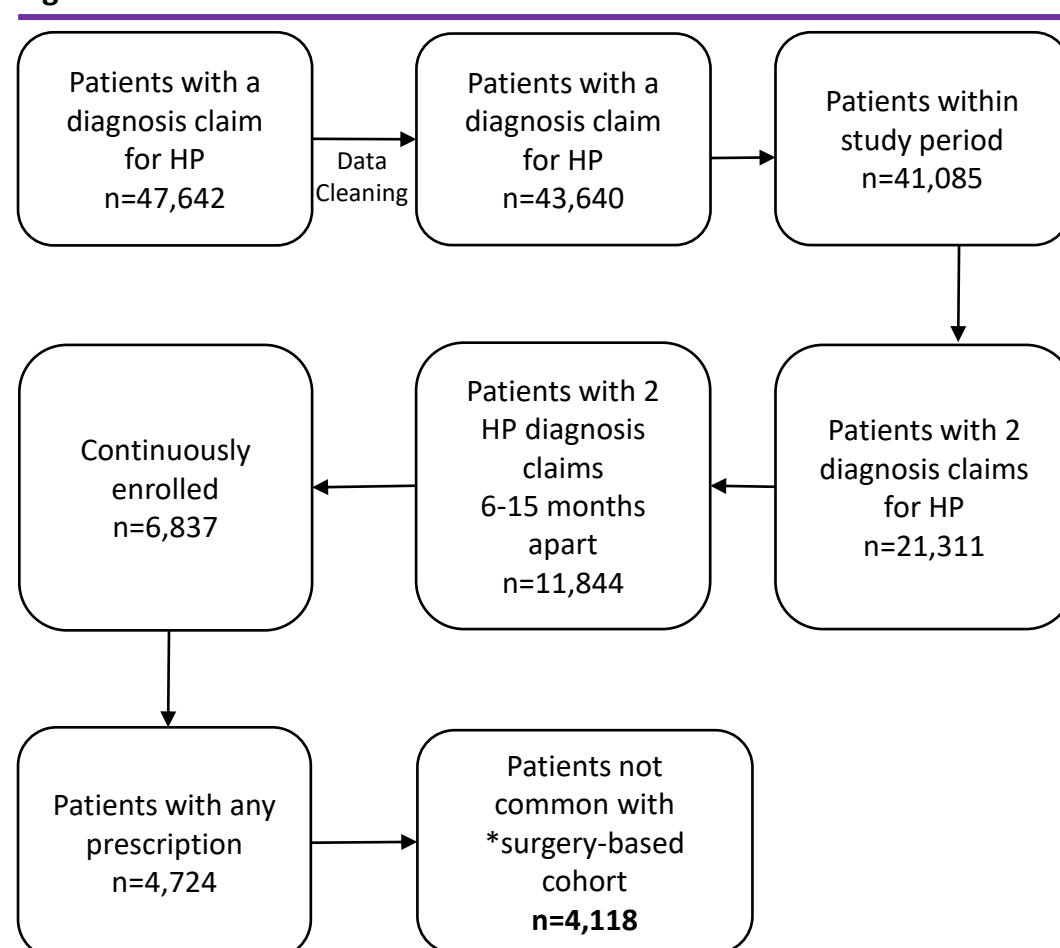


- Outcomes:**
 - Comorbidities and conditions of interest:** Presence of ICD9/10 diagnostic codes for each specific condition of interest.
 - Laboratory and Procedure Utilization:** ICD9/10 Procedure Codes, Healthcare Common Procedure Coding System (HCPCS) or Common Procedural Technology (CPT)
 - Treatment Patterns:** Presence of a claim with a National Drug Code (NDC) or HCPCS code.
- Analysis:** All outcomes were assessed up to one year from the index date. Baseline characteristics and outcomes were compared by descriptive statistics.

RESULTS

- Out of 43,640 patients with a diagnosis claim for HP, 4,118 patients met the eligibility criteria (Figure 2).
- The mean age of this cohort was 56.5 years, and 76.4% were females (Table 1). Patients were uniformly distributed between regions with slightly higher proportion in the West (28.1%).

Figure 2. Patient Selection Flowchart



* This study utilized an additional surgery-based approach to identify cHP patients, the findings of that cohort are included in ENDO poster titled "Clinical Burden and Practice Patterns in Patients With Chronic Hypoparathyroidism in the United States (US): A Claims Data Analysis Using Surgery-Based Criteria"

Table 1. Baseline Characteristics

	N=4,118
Female, n (%)	3,146 (76.4%)
Age (Years), Mean (Standard Deviation)	56.5 (18.6)
	≤40 790 (19.2%)
	41-50 613 (14.9%)
	51-60 842 (20.5%)
	>60 1,873 (45.5%)
Charlson Co-morbidity Index, Mean (Standard Deviation)	2.16 (2.5)
Insurance type, n (%)	
	Commercial 1,591(38.6%)
	Medicaid 1,307 (31.7%)
	Medicare Advantage 1,067 (25.9%)
	Unknown 152 (3.7%)

Table 2. Comorbidities

	1- Year Baseline (N=4,118)		Follow-up Index to 1 Year (N=4,118)	
	n	%	n	%
Cardiovascular and metabolic disorders				
Cardiac arrhythmias	551	13.4%	717	17.4%
Congestive Heart Failure	321	7.8%	433	10.5%
Diabetes	1,024	24.9%	1,209	29.4%
Hypertension	2,052	49.8%	2,306	56.0%
Peripheral Vascular Disease	307	7.5%	355	8.6%
CNS disorders				
Seizures and convulsions	121	2.9%	226	5.5%
Cerebrovascular disease	246	6.0%	315	7.6%
Gastrointestinal disorders				
Constipation	222	5.4%	456	11.1%
Imbalance of calcium				
Hypercalcemia	232	5.6%	338	8.2%
Hypocalcemia	1,247	30.3%	1,593	38.7%
Liver disease				
Mild liver disease	226	5.5%	337	8.2%
Neuropsychiatric disorders				
Anxiety	700	17.0%	891	21.6%
Depressive disorders	730	17.7%	904	22.0%
Sleep-wake disorders	632	15.3%	758	18.4%
Any malignancy	1063	25.8%	1254	30.5%
Any malignancy: Thyroid Cancer	832	78.3%	990	78.9%
Musculoskeletal disorders				
Osteoporosis	317	7.7%	396	9.6%
Renal disease				
CKD (Stage 1-4, unspecified)*	629	15.3%	825	20.0%
Kidney failure (CKD Stage V, ESRD and failure)*	162	3.9%	206	5.0%
Nephrolithiasis/renal stones	214	5.2%	278	6.8%
Respiratory disease				
Chronic pulmonary disease	884	21.5%	992	24.1%
COPD	376	9.1%	425	10.3%
Rheumatic disease	284	6.9%	345	8.4%

*Possible overlap as CKD unspecified included patients with claims with CKD diagnosis without specific stage.

Table 3. Treatment Patterns

	1- Year Baseline (N=4,118)		Follow-up Index to 1 Year (N=4,118)	
	n	%	n	%
Any Vitamin D				
Calcitriol	2,065	50.1%	2,493	60.5%
Ergocalciferol	508	12.3%	646	15.7%
Parathyroid hormone				
Abaloparatide	0	0.0%	0	0.0%
rhPTH(1-84)	62	1.5%	141	3.4%
Teriparatide	9	0.2%	11	0.3%
Thyroid Replacement Therapy	2,501	60.7%	2,763	67.1%

Table 4. Number of patients with at least one lab test

	1- Year Baseline (N=4,118)		Follow-up Index to 1 Year (N=4,118)	
	n	%	n	%
Any serum calcium	3,203	77.8%	3,701	89.9%
Any serum eGFR/creatinine	3,051	74.1%	3,528	85.7%
Vitamin D [25(OH)D/1,25(OH)2D]	1,863	45.2%	2,569	62.4%
Parathyroid hormone, intact	1,321	32.1%	1,806	43.9%
Serum magnesium	1,086	26.4%	1,457	35.4%
Serum phosphorus	1,051	25.5%	1,496	36.3%
Bone mineral density	338	8.2%	449	10.9%
Serum albumin	311	7.6%	484	11.8%
Urine calcium, 24 hours	224	5.4%	431	10.5%
Bone formation and resorption markers	144	3.5%	223	5.4%

Table 5. Mean number of lab tests among those who had a lab test

	1- Year Baseline (N=4,118)		Follow-up Index to 1 Year (N=4,118)	
	Mean	SD	Mean	SD
Any serum calcium	3.9	5.0	5	8.2
Any serum eGFR/creatinine	3.6	4.7	4.6	7.8
Vitamin D [25(OH)D/1,25(OH)2D]	1.7	1.8	2.01	1.4
Parathyroid hormone, intact	1.9	1.6	2.1	2.4

CONCLUSION

- This study employed a large US claims database with a sizeable number of HP claims and used rigorous inclusion and exclusion criteria to identify a cHP population.
- Findings provide insights on a cohort of patients of cHP that were identified using a diagnosis-based approach, of which, most patients seemed to be prevalent cases. The demographics of the patient population were consistent with literature.
- These data highlight the substantial comorbidity burden in this patient population that aligned with the monitoring patterns.
- Kidney health appears to be a significant concern in this patient population and could be considered a key target organ for monitoring and therapeutic intervention.
- Future studies can compare the findings with a control group and examine the healthcare resource utilization and costs associated with the disease and its complications.

DISCLOSURES

Study was funded by Amolyt Pharma. PL, MDC, SA and BW are current employees of Amolyt Pharma. DS and KLD are employees of EPI-Q Inc., which received payment from Amolyt Pharma associated with the development and execution of this study. DMM and MM were scientific advisors on this study, and they received an honorarium from Amolyt Pharma. Poster presented at ENDO 2021, March 20-23 [Virtual]