

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

A Claims Data Analysis Using Surgery-Based Criteria

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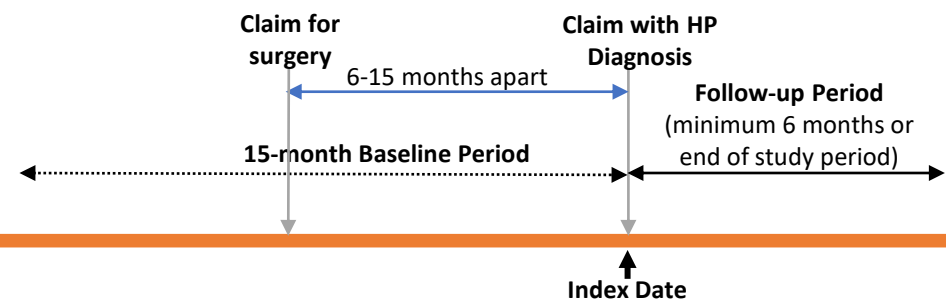
INTRODUCTION

- 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 surgery-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 a claim with a procedure code for parathyroidectomy, complete or partial thyroidectomy, or neck dissection, followed by a claim with a diagnosis of HP (E20.0, E20.8, E20.9, E89.2, 252.1), 6-15 months apart; with a subsequent second HP diagnosis claim at any time point
 - Index date: Date of the first qualifying HP diagnosis claim
 - Patients continuously enrolled for 15 months before the index date and a minimum of 6 months after the index date

Figure 1. Eligibility Criteria



- Outcomes:** In addition to baseline characteristics, following outcomes were assessed:
 - Comorbidities and conditions of interest:** Presence of ICD9/10 diagnostic codes for each specific condition of interest.
 - Laboratory and Procedure Utilization:** Presence of procedure codes, including, ICD9/10 Procedure Codes, Healthcare Common Procedure Coding System (HCPCS) or Common Procedural Technology (CPT), for each specific test.
 - 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 assessed by descriptive statistics.

RESULTS

A total of 1,406 patients met the eligibility criteria, among which 1,184 patients had complete data for 1-year follow-up. The mean time between surgery and qualifying HP diagnosis claim was 8.7 + 2.3 (SD) months, and 115 patients (8.2%) had an HP diagnosis prior to surgery.

Figure 2. Patient Selection Flowchart

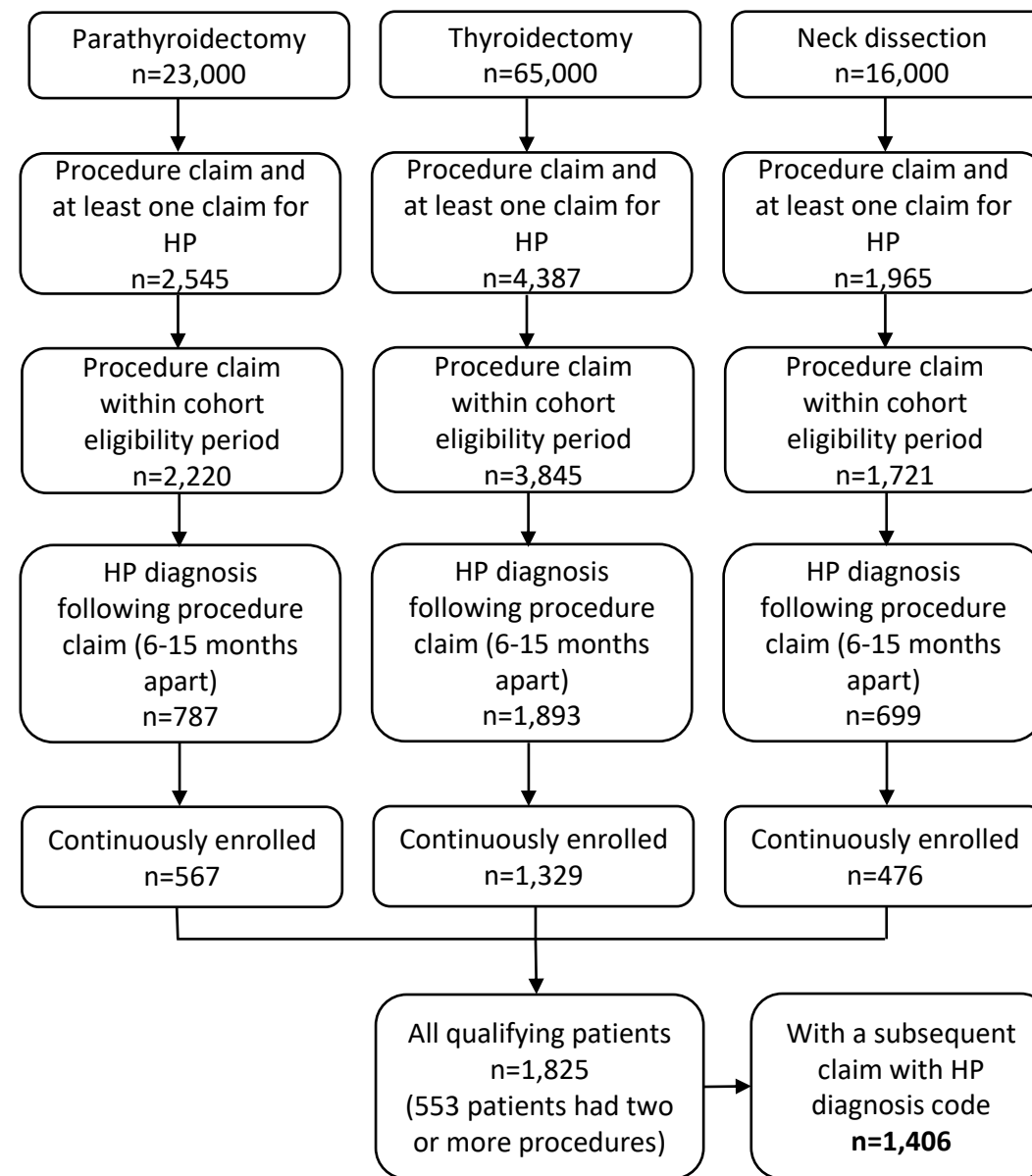


Table 1. Baseline Characteristics

	N=1,406
Female, n (%)	1,170 (83.2%)
Age (Years), Mean (SD)	52.1 (16.4)
	≤40 353 (25.1%)
	41-50 292 (20.8%)
	51-60 309 (22.0%)
	>60 452 (32.1%)
Charlson Co-morbidity Index, Mean (SD)	4.12 (3.6)
Insurance type, n (%)	
	Commercial 743 (52.8%)
	Medicaid 397 (28.3%)
	Medicare Advantage 220 (15.7%)
	Unknown 42 (2.9%)

Table 2. Comorbidities

	Before Surgery (1 Year) N=1,069		Between Surgery and Index N=1,406		Follow-up Index – 1 Year N=1,184	
	n	%	n	%	n	%
Cardiovascular and metabolic disorders						
Cardiac arrhythmias	195	18.2%	288	20.5%	218	18.4%
Congestive Heart Failure	60	5.6%	110	7.8%	83	7.0%
Diabetes	219	20.5%	303	21.6%	257	21.7%
Diabetic Nephropathy	87	8.1%	127	9.0%	122	10.3%
Hypertension	485	45.4%	707	50.3%	588	49.7%
Peripheral Vascular Disease	54	5.1%	84	6.0%	58	4.9%
CNS disorders						
Cerebrovascular Disease	66	6.2%	90	6.4%	82	6.9%
Gastrointestinal disorders						
Constipation	83	7.8%	152	10.8%	123	10.4%
Imbalance of calcium						
Hypercalcemia	142	13.3%	232	16.5%	103	8.7%
Hypocalcemia	77	7.2%	945	67.2%	558	47.1%
Liver disease						
Mild liver disease	87	8.1%	105	7.5%	118	10.0%
Neuropsychiatric disorders						
Anxiety	236	22.1%	357	25.4%	283	23.9%
Depressive disorders	202	18.9%	304	21.6%	258	21.8%
Sleep-wake disorders	190	17.8%	278	19.8%	247	20.9%
Any malignancy	457	42.8%	795	56.5%	642	54.2%
Any malignancy: Thyroid Cancer	379	82.9%	727	91.4%	580	90.3%
Musculoskeletal disorders						
Osteoporosis	95	8.9%	120	8.5%	116	9.8%
Renal disease						
CKD (Stage 1-4, unspecified)*	87	8.1%	155	11.0%	142	12.0%
Kidney failure (CKD Stage V, ESRD and failure)*	44	4.1%	65	4.6%	51	4.3%
Nephrolithiasis/renal stones	65	6.1%	72	5.1%	83	7.0%
Respiratory disease						
Chronic Pulmonary Disease	235	22.0%	329	23.4%	259	21.9%
COPD	85	7.9%	118	8.4%	90	7.6%
Rheumatic disease	53	5.0%	66	4.7%	65	5.5%

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

Table 3. Treatment Patterns

	Before Surgery (1 Year) N=1,069		Between Surgery and Index N=1,406		Follow-up Index – 1 Year N=1,184	
	n	%	n	%	n	%
Any Vitamin D						
Calcitriol	84	7.9%	950	67.6%	611	51.6%
Ergocalciferol	147	13.8%	217	15.4%	157	13.3%
Parathyroid hormone						
Abaloparatide	0	0.0%	0	0.0%	0	0.0%
rhPTH(1-84)	2	0.2%	24	1.7%	65	5.5%
Teriparatide	1	0.1%	3	0.2%	4	0.3%
Thyroid Replacement Therapy	228	21.3%	960	68.3%	792	66.9%

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

	Before Surgery (1 Year) N=1,069		Between Surgery and Index N=1,406		Follow-up Index – 1 Year N=1,184	
	n	%	n	%	n	%
Any serum calcium	890	83.3%	1,343	95.5%	1,103	93.2%
Any serum eGFR/creatinine	878	82.1%	1,220	86.8%	1,021	86.2%
Parathyroid hormone, intact	331	31.0%	1,156	82.2%	746	63.0%
Vitamin D [25(OH)D/1,25(OH)2D]	499	46.7%	922	65.5%	793	67.0%
Serum magnesium	212	19.8%	785	55.8%	484	40.9%
Serum phosphorus	178	16.7%	698	49.6%	455	38.4%
Serum albumin	63	5.9%	338	24.0%	176	14.9%
Urine calcium, 24 hours	88	8.2%	77	5.5%	99	8.4%
Bone formation and resorption markers	50	4.7%	60	4.3%	54	4.6%

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

	Before Surgery (1 Year) N=1,069		Between Surgery and Index N=1,406		Follow-up Index – 1 Year N=1,184	
	Mean	SD	Mean	SD	Mean	SD
Any serum calcium	4	8.3	7.9	7.8	5.5	6.3
Any serum eGFR/creatinine	3.7	4.2	5.2	6.2	4.6	4.9
Vitamin D [25(OH)D/1,25(OH)2D]	1.7	1.1	2.2	1.9	2.2	1.7
Parathyroid hormone, intact	2.1	1.7	3.8	3.7	2.3	1.8

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 surgery-based approach, of which, most patients seemed to be incident 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]