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Variations in Clinical Practice Patterns for Hypoparathyroidism

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INTRODUCTION

- Chronic hypoparathyroidism (cHP) is a rare disease characterized by a deficiency in parathyroid hormone (PTH) that results in low serum calcium.¹⁻³
- cHP is typically caused by surgery to remove a thyroid tumor or the parathyroid glands but can also arise as a result of having to other conditions such as autoimmune disease, cancer, and congenital conditions, as well as idiopathic causes.¹⁻³
- Emerging evidence regarding optimal treatment for patients with cHP has led to the development of updated evaluation and management guidelines in 2022.⁴
- Yet, few studies to date have characterized the practice patterns of patients with cHP.
- **Study Objective:** To determine how current practice patterns for individuals with cHP compare with the updated guidelines.

METHODS

- Study Design: Non-interventional retrospective claims database analysis and chart review
- Claims Database Methods
- 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 based on the following:
 - Presence of a claim with a diagnosis of HP (E20.0, E20.8, E20.9, E89.2, 252.1) 6-15 months following a claim for parathyroidectomy, complete or partial thyroidectomy, or neck dissection procedure or from a second HP claim
- 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
- Analysis: Baseline characteristics were assessed 1-year pre-index and outcomes were assessed up year 2 post-index date. All were analyzed with descriptive statistics.
- Chart Review Methods
- Source: 103 endocrinologists and nephrologists (US=40, UK=21, France=21, Germany=21) were surveyed and conducted chart reviews with each participant contributing data for last 5 patients with cHP seen in their practice
- Study Period: January 18, 2021 February 22, 2021
- Study Population: Patients identified with cHP based on the following:
- 4 patients whose cHP is related to a neck surgery and 1 patient for who
 cHP is not related to a neck surgery
- Physicians contributed data for the time the patient was in their care

Analysis: All outcomes were assessed based on the time the patient was in the physician's care. Baseline characteristics and outcomes were analyzed with descriptive statistics.

RESULTS

- A total of 5,302 patients met criteria for cHP from the claims database study and 515 cHP patients were included in the chart review study, Table 1.
- The average age in both data sets was in the 50s (55.5 years claims database; 52.0 years chart review) and majority of patients were female (81% claims database; 66% chart review).

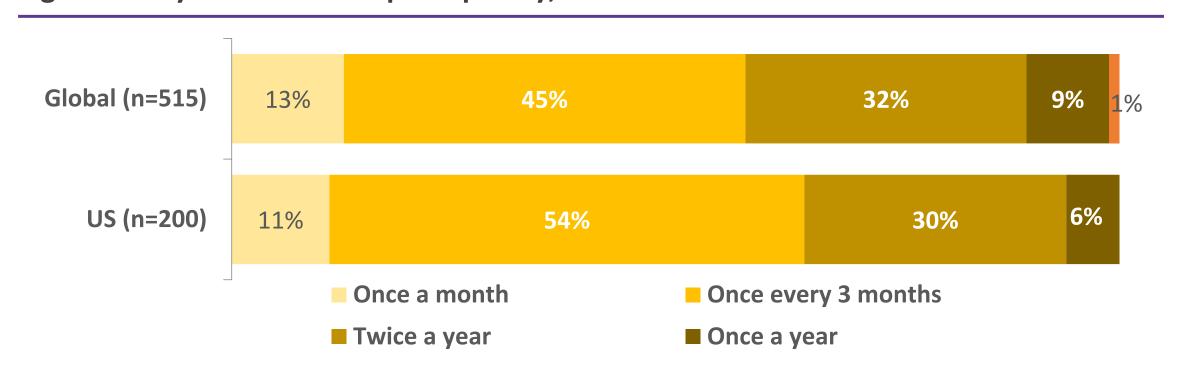
Table 1. Characteristics

	Claims Database N=5,302	Chart Review N=515
Female, n (%)	4,316 (81%)	340 (66%)
Average age (Years)	55.5	52.0
Comorbid conditions, n (%)*	N=5,187	N=515
Chronic kidney disease	1,640 (32%)	134 (26%)
Cardiovascular disease	2,720 (52%)	67 (13%)
Neuropsychiatric disease	2,118 (41%)	41 (8%)
Fractures	145 (3%)	21 (4%)

*Claims database comorbidities are based on claims from the 1-year pre-index period and not all patients had a full 1-year of data. The chart review data included physician documentation of current medical complications and comorbidities and/or risk factors.

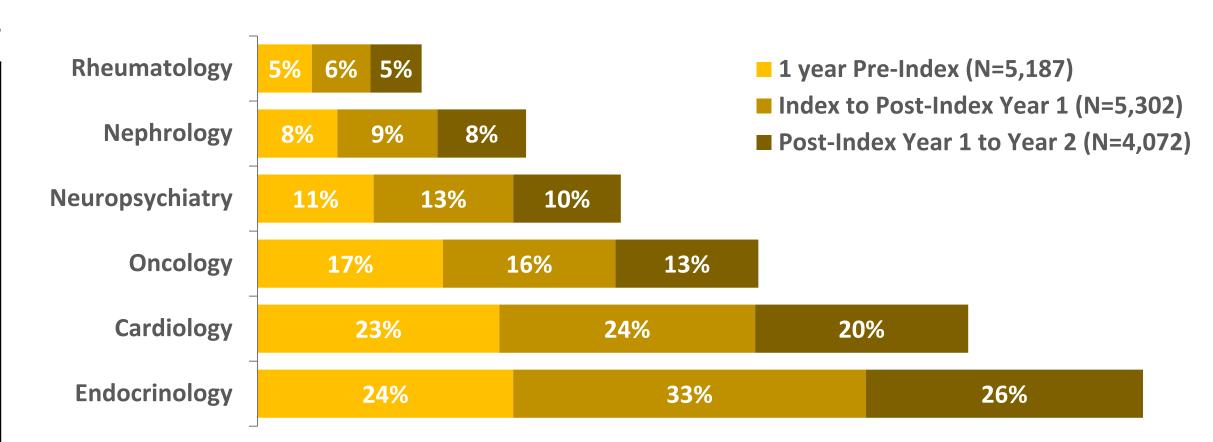
- Of the physician specialists recruited to contribute data for the chart review, 78% were endocrinologists and 22% were nephrologists with a combined average of 20 years in practice.
- 93% of the participating physicians report being the decision maker for their patients with cHP.
- 90% of the global patients were seen at least twice per year, Figure 1. The US physician follow-up was similar to the global patterns in the chart review study.

Figure 1. Physician Follow-up Frequency, Chart Review



• Figure 2 illustrates physician specialty utilization for any reason by cHP patients in the pre- and post-index periods in the claims database study. A higher percentage of cHP patients were seen by an endocrinologist and nephrologist between index and post-index year 1.

Figure 2. Physician Specialty Utilization for Any Reason, Claims Database



*Not all patients had 1-year of data in the pre-index period or the post-index year 1 to year 2 period.

- Figure 3 displays the proportion of patients that reported having the measure monitored at least once in the index to Year 1 period for the claims database study and several times a year for the chart review patients.
- The frequency of patients receiving bone health monitoring in the claims database study and chart review was 11% and 6% for bone mineral density; and 5% and 9% for bone markers, respectively.

Figure 3. Monitoring Practices

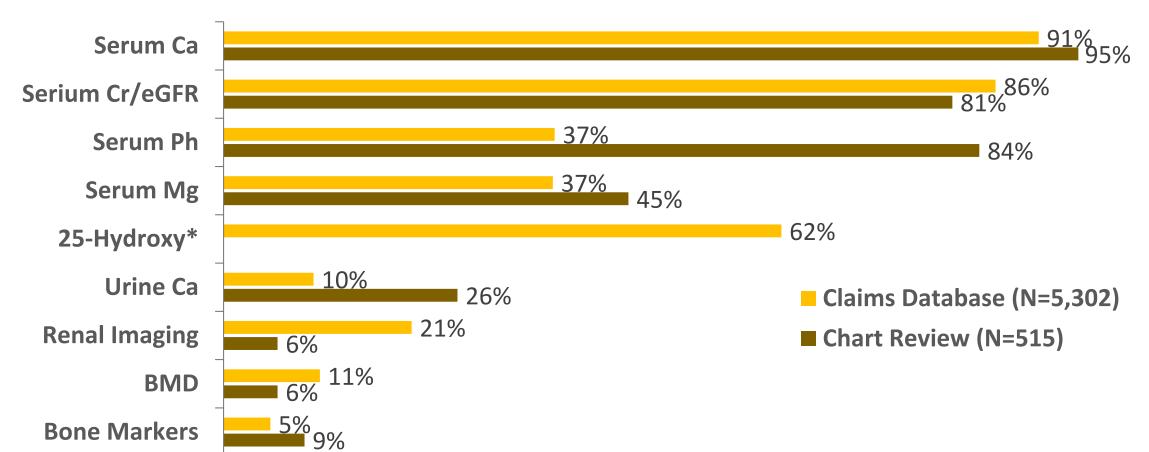


Chart review: proportion of patients that were measured at least once per year Claims database: proportion of patients with at least one claim in the index to Year 1 period *25-Hydroxyvitamin D data was not collected in the chart review

CONCLUSIONS

- The 2nd International Guidelines on Hypoparathyroidism published in 2022 recommend routine biochemical monitoring of serum levels ionized or albumin-adjusted calcium (Ca), phosphate (Ph), magnesium (Mg), creatinine (Cr), and estimated glomerular filtration rate (eGFR) every 3-12 months for stable patients.⁴
- These studies show routine monitoring of serum Ca and serum Cr/eGFR is consistent with the guidelines. However, there are some mixed results and discordance with the monitoring of serum Ph and Mg.
- Over 90% of patients primarily managed by endocrinologists and nephrologists see these specialists more than twice per year. Whereas only 28% of cHP patients in the claims database were seen by an endocrinologist and less than 10% were seen by a nephrologist once per year.
- The different data sources may account for some of the differences in practice patterns but also highlight potential gaps in care.
- Overall, our data underscore challenges with optimizing care for patients with this rare disorder.
- In addition, they suggest that ongoing efforts to educate both patients and physicians about management guidelines may improve care and ultimately enhance health and quality of life in cHP.

DISCLOSURES

Study was funded by Amolyt Pharma. NL, PL, MDC, SA and BW are current employees of Amolyt Pharma. KLD is an employee of EPI-Q Inc., which received payment from Amolyt Pharma associated with the development and execution of this study. DMM was a scientific advisor on this study and received an honorarium from Amolyt Pharma.

REFERENCES

- 1. Powers J, et al. *J Bone Miner Res*. 2013;28(12):2570-2576.
- 2. Clarke BL, et al. JCEM. 2016;101(6):2284-2299.
- 3. Shoback DM, et al. *JCEM*. 2016;101(6):2300-2312.
- 4. Khan AA, et al. *J Bone Miner Res*. 2022;37(12):2568-2585.

Abbreviations: 25-Hydroxy= 25-Hydroxyvitamin D; BMD = Bone Mineral Density; Ca = Calcium; Cr = Creatinine; eGFR = estimated Glomerular Filtration Rate; Mg = Magnesium; Ph = Phosphate; US = United States



Presented at the ENDO 2023; June 15-18, 2023; Chicago, Illinois