The clinical burden of hypoparathyroidism (cHP) remains poorly described due to the rarity of this condition.

The goal of this study was to further investigate the clinical characteristics of patients with chronic hypoparathyroidism (cHP) using patients with transient post-surgical hypoparathyroidism (HYP) as a reference.

**INTRODUCTION**

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**METHODS**

Study Design: Non-interventional retrospective claims data analysis

Data Source: HealthVault closed claim payer medical and pharmacy database (Private Source 20) with 130 million covered lives

Study Period: July 1, 2010 - December 31, 2019

Study Population: Incident and prevalent patients identified with HYP

Eligibility criteria were adapted from a study by Powers et al. (1) and defined under the guidance of clinicians experienced in treating patients with cHP. Patients were continuously enrolled 21 year pre-post index.

Incident HYP (reference group)

- Patients having a claim for parathyroidectomy, complete or partial thyroidectomy, or neck dissection followed by a claim with a diagnosis of HP within 6 months of the procedure, with no HP diagnosis claim before the procedure and 6 months after the procedure

Index date: Date of the last HP diagnosis claim before the procedure

Incident cHP

- Patients having a claim for parathyroidectomy, complete or partial thyroidectomy, or neck dissection followed by a claim with an HP diagnosis between the index date and a 2-month period, and a second HP diagnosis claim at any subsequent time point

Index date: Date of the first qualifying HP diagnosis claim

Prevalent cHP

- Patients having 2 claims for HP that were 6-15 months apart and that had a prescription claim for either active vitamin D, calcium, PTTH or thyroid replacement therapy between the first qualifying HP claim and within 30 days of the second HP claim

Methods: Claims analysis using de-identified data from patients with qualifying HP diagnoses.

Analysis: All outcomes were assessed up to one year from the index date. Baseline characteristics and outcomes were compared using descriptive statistics.

**RESULTS**

- Of the 43,660 patients with a diagnosis claim for HP in the claims database during the study period, a total of 6,297 individuals met the inclusion criteria of the study and were further divided into three cohorts: incident HYP (N=773), incident cHP (N=4,486), and prevalent cHP (N=1,411) (Table 1).

  - The time between surgery and HP claim that qualified the patient for eligibility was 2.0 (1.7) months for the incident HP cohort and 8.7 (2.3) months for the incident cHP cohort. In prevalent cHP cohort, 3.4% had a record of neck surgery in the year before the index.

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Incident HP</th>
<th>Incident cHP</th>
<th>Prevalent cHP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (%)</td>
<td>624 (91.0%)</td>
<td>5,275 (93.7%)</td>
<td>2,146 (79.4%)</td>
</tr>
<tr>
<td>Age (Years), Mean (SD)</td>
<td>53.5 (14.3)</td>
<td>53.2 (14.6)</td>
<td>56.5 (18.8)</td>
</tr>
<tr>
<td>Insurance type, n (%)</td>
<td>452 (35.9%)</td>
<td>742 (16.8%)</td>
<td>871 (30.1%)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>204 (26.4%)</td>
<td>197 (26.3%)</td>
<td>1,057 (37.1%)</td>
</tr>
<tr>
<td>Medicare Advantage</td>
<td>87 (11.3%)</td>
<td>220 (15.7%)</td>
<td>1,057 (37.1%)</td>
</tr>
<tr>
<td>Procedure, n (%)</td>
<td>50 (18.1%)</td>
<td>132 (22.6%)</td>
<td>132 (22.6%)</td>
</tr>
<tr>
<td>Parathyroidectomy</td>
<td>229 (17.0%)</td>
<td>568 (29.2%)</td>
<td>119 (64.1%)</td>
</tr>
<tr>
<td>Neck dissection</td>
<td>50 (18.1%)</td>
<td>132 (22.6%)</td>
<td>132 (22.6%)</td>
</tr>
<tr>
<td>Thyroidectomy</td>
<td>448 (57.9%)</td>
<td>706 (20.2%)</td>
<td>132 (22.6%)</td>
</tr>
</tbody>
</table>

Treatment Patterns

- CaCl2 was the most frequently used prescription vitamin D therapy, and PTTH replacement therapy was prescribed for less than 5% of patients (Table 2).

Table 2. Treatment Patterns

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Incident HP</th>
<th>Incident cHP</th>
<th>Prevalent cHP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>103 (15.8%)</td>
<td>103 (15.8%)</td>
<td>505 (25.5%)</td>
</tr>
<tr>
<td>Parathyroidectomy</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Terfenadine (Tera)**</td>
<td>1.0%</td>
<td>1.0%</td>
<td>11.0%</td>
</tr>
</tbody>
</table>

**CONCLUSIONS**

- This study provides insights into the natural history of HP and demonstrates cHP is associated with increased disease burden and medical needs in contrast to patients with HYP.

- The characteristics of cHP patients were consistent with prior report (1, 3-6) that the majority of cHP patients were female with mean age consistent with parathyroid or thyroidectomy and treated in line with current treatment guidelines.

- During the follow up periods, cHP cohorts had a higher incidence of hypocalcemia and cardiac arrhythmia compared to the HYP cohort.

- While hypoparathyroidism is associated with increases in bone mineral density, almost 10% of patients in this cohort were diagnosed with osteoporosis.

- Given the noted increased burden and of monitoring for renal disease in the prevalent cHP cohort, this could be a consistent key target for renal therapeutic intervention.

- The strength of this study lies in the inclusiveness of the US HP patient population and the rigorous eligibility criteria for the identification of cHP patients. Limitations that are common among claims analysis studies also apply to the present study.

- Future studies could examine the costs associated with HP and its complications.

**Comorbidities**

- Before surgery, ≥25% differences between the incident and HP cohorts were observed for the following conditions: hyper- and hypocalcemia, any malignancy, and any disease in particular thyroid cancer.

- As expected, in the 1 to 2 years following an incident diagnosis, there was a decrease in the rate of hypocalcemia and an increase in the rate of hypercalcemia compared to baseline, and in line with rates observed in the prevalent cHP cohort.

- While HP patients have, on average, an increased bone mineral density (T), it is interesting to note that cHP patients are not immune to osteoporosis, as about 51% of the prevalent cHP cohort were diagnosed with osteoporosis.

- The prevalence of CKD stages 1-4 was approximately two-fold higher in the prevalent HP cohort during the study period compared to the incident and prevalent cHP cohorts.

**Disclosures**

Study was funded by Amolty Pharma, PL, MSD, SA and BW are current employees of Amolty Pharma. KLD is an employee of EPI-Q Inc., which received payment from Amolty Pharma associated with the development and execution of this study. OMM was a scientific advisor to this research and received an honorarium from Amolty Pharma. Poster presented at ASBMR 2021, Oct 1-4 (Virtual Presentation).


**Abbreviations**: cHP: Chronic Hypoparathyroidism; CKD: Chronic Kidney Disease; eGFR: Estimated Glomerular Filtration Rate; ESRD: End-stage Renal Disease; HP: Hypoparathyroidism; PTTH: Patient; SD: Standard Deviation; HYP: Transient Hypoparathyroidism; 1,25(OH)2D3: 1,25-dihydroxyvitamin D3; 25OHD: 25-hydroxyvitamin D.