cHP Natural History Study: ISPOR Poster

TITLE
Methods to Identify Patients with Chronic Hypoparathyroidism in the United States (US) Using Claims Data

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DISCLOSURES
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MEETING
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INTRODUCTION:

- Chronic hypoparathyroidism (cHP) is a rare disorder that is characterized by abnormally low parathyroid hormone (PTH) concentration and consequent low serum calcium levels (1).
- Largely stemming from hypocalcemia, cHP symptoms can result in spasms, tetany, paraesthesia, seizures or cardiac arrhythmias (2,3). Long term complications associated with cHP and its treatment include chronic renal disease, calcifications in kidneys and brain, and deteriorated quality of life (2,4).
- Most cHP patients are treated with conventional therapy, including oral calcium and active vitamin D, with the aim of managing the symptoms and reducing complications (5,6).
- Very few studies to date have characterized cHP patient populations (4,7,8,9).

Study Objective: This study employed two strategies to identify and describe cHP population 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. The patients include those enrolled in Commercial, Medicare Advantage, or Medicaid plans
- Study Period: October 1, 2014 - December 31, 2019
- Study Population: The study population included patients identified with cHP using two approaches, diagnosis- based (Method 1) and surgery-based (Method 2). These approaches were employed to identify the maximum number of cHP patients. Eligibility criteria for Methods 1 and 2 were adapted from a study by Powers et al (10) and defined under the guidance of clinicians experienced in treating patients with cHP.
  - Method 1: Diagnosis-based approach (Figure 1)
    - Patients with ≥2 claims with diagnosis of HP that were 6-15 months apart (International Classification of Diseases, ICD 9/10 codes: E20.0, E20.8, E20.9, 252.1) and that had a prescription claim for either active vitamin D, calcium, PTH or thyroid replacement therapy between the first HP claim and within 30 days of the second HP claim
    - Index date: Date of the first of two qualifying HP diagnosis claims
    - Continuously enrolled for a year before the index date and a minimum of 16 months after the index date

Figure 1. Eligibility Criteria for Method 1 (Diagnosis-based Approach)
Method 2: Surgery-based approach (Figure 2)
- Patients with 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 with a minimum of 6 months after the index date

Figure 2. Eligibility Criteria for Method 2 (Surgery-based Approach)

- Analysis: Patient characteristics and demographics were assessed for both cohorts.

RESULTS:
- Among 43,640 patients with ≥1 diagnosis claim for HP, 4,118 were identified as cHP patients by Method 1 (606 common patients with Method 2 were excluded) and 1,406 by Method 2 (Figures 3 and 4).
- Method 1 patients had a mean age of 56.5 years and 76.4% were females, whereas Method 2 patients were 52.1 years old on average and 83.2% were females. Approximately 30% of the subjects identified in both cohorts were Medicaid patients. Method 2 cohort patients had a higher proportion of patients with a Commercial Insurance plan and a lower proportion with Medicare Advantage as compared with Method 1 cohort. The patients were largely distributed uniformly between regions with a slightly higher proportion in the West (Method 1) and South (Method 2) (Table 1).
- The mean Charlson Comorbidity Index (CCI) in Methods 1 and 2 patients were 2.16 and 4.12. Around 55% Method 2 patients had a CCI≥3.
Figure 3. Patient Selection Flowchart for Method 1 (Diagnosis-based Approach)

Data Cleaning

Patients with a diagnosis claim for HP
n=47,642

Patients with a diagnosis claim for HP
n=43,640

Patients within study period
n=41,085

Continuously enrolled
n=6,837

Patients with 2 HP diagnosis claims 6-15 months apart
n=11,844

Patients with 2 diagnosis claims for HP
n=21,311

Patients with any prescription
n=4,724

Patients not common with surgery-based cohort
n=4,118
**Figure 4. Patient Selection Flowchart for Method 2 (Surgery-based Approach)**

- **Parathyroidectomy**
  - Procedure claim and at least one claim for HP
    - Procedure claim within cohort eligibility period
      - HP diagnosis following procedure claim (6-15 months apart)
        - Continuously enrolled
          - All qualifying patients
            - n=1,825
              (553 patients had two or more procedures)
  - With a subsequent claim with HP diagnosis code
    - n=1,406

- **Thyroidectomy**
  - Procedure claim and at least one claim for HP
    - Procedure claim within cohort eligibility period
      - HP diagnosis following procedure claim (6-15 months apart)
        - Continuously enrolled
          - All qualifying patients
            - n=1,825
              (553 patients had two or more procedures)

- **Neck dissection**
  - Procedure claim and at least one claim for HP
    - Procedure claim within cohort eligibility period
      - HP diagnosis following procedure claim (6-15 months apart)
        - Continuously enrolled
          - All qualifying patients
            - n=1,825
              (553 patients had two or more procedures)
Table 1: Baseline Characteristics of Method 1 (Diagnosis-based) and Method 2 (Surgery-based) Cohorts

<table>
<thead>
<tr>
<th></th>
<th>Method 1 Cohort (N=4,118)</th>
<th>Method 2 Cohort (N=1,406)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>3,146 (76.4%)</td>
<td>1,170 (83.2%)</td>
</tr>
<tr>
<td>Age (Years), Mean (SD)</td>
<td>56.5 (18.6)</td>
<td>52.1 (16.4)</td>
</tr>
<tr>
<td>≤40</td>
<td>790 (19.2%)</td>
<td>353 (25.1%)</td>
</tr>
<tr>
<td>41-50</td>
<td>613 (14.9%)</td>
<td>292 (20.8%)</td>
</tr>
<tr>
<td>51-60</td>
<td>842 (20.5%)</td>
<td>309 (22.0%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>1,873 (45.5%)</td>
<td>452 (32.1%)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index, Mean (SD)</td>
<td>2.16 (2.5)</td>
<td>4.12 (3.6)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1,377 (33.4%)</td>
<td>223 (15.9%)</td>
</tr>
<tr>
<td>1</td>
<td>593 (14.4%)</td>
<td>141 (10.0%)</td>
</tr>
<tr>
<td>2</td>
<td>857 (20.8%)</td>
<td>273 (19.4%)</td>
</tr>
<tr>
<td>≥3</td>
<td>1,291 (31.3%)</td>
<td>769 (54.7%)</td>
</tr>
<tr>
<td>Insurance type, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>1,591 (38.6%)</td>
<td>743 (52.8%)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>1,307 (31.7%)</td>
<td>397 (28.3%)</td>
</tr>
<tr>
<td>Medicare Advantage</td>
<td>1,067 (25.9%)</td>
<td>220 (15.7%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>152 (3.7%)</td>
<td>42 (2.9%)</td>
</tr>
<tr>
<td>Procedures, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parathyroidectomy</td>
<td>139 (3.4%)</td>
<td>368 (26.2%)</td>
</tr>
<tr>
<td>Neck dissection</td>
<td></td>
<td>332 (23.6%)</td>
</tr>
<tr>
<td>Thyroidectomy</td>
<td></td>
<td>706 (50.2%)</td>
</tr>
<tr>
<td>Time between surgery and HP claim that qualified the patient for eligibility (Months), Mean (SD)</td>
<td>-</td>
<td>8.7 (2.3)</td>
</tr>
<tr>
<td>Patients with HP Code before surgery</td>
<td>N/A</td>
<td>115 (8.2%)</td>
</tr>
<tr>
<td>Region, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwest</td>
<td>875 (21.2%)</td>
<td>374 (26.6%)</td>
</tr>
<tr>
<td>Northeast</td>
<td>990 (24.0%)</td>
<td>312 (22.2%)</td>
</tr>
<tr>
<td>South</td>
<td>1,002 (24.3%)</td>
<td>414 (29.4%)</td>
</tr>
<tr>
<td>West</td>
<td>1,158 (28.1%)</td>
<td>286 (20.3%)</td>
</tr>
<tr>
<td>Alaska</td>
<td>1 (0.1%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Hawaii</td>
<td>19 (0.5%)</td>
<td>3 (0.2%)</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>72 (1.7%)</td>
<td>17 (1.2%)</td>
</tr>
</tbody>
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HP: Hypoparathyroidism; SD: Standard Deviation

CONCLUSION

- This study, employing a large US claims database with a sizeable number of HP claims and utilizing two methodologies, successfully identified a significant cHP population.
- The demographics of the identified patient population were consistent with reports in the literature. In the Method 1 cohort, most patients seemed to be prevalent cases, whereas in the Method 2 cohort, the majority of cHP patients were newly diagnosed.
- Further analysis is underway to assess practice patterns and both clinical and economic burden associated with cHP in these two identified cHP populations.
REFERENCES