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PREVALENCE OF COMPLICATIONS AND TREATMENT IN ACROMEGALY PATIENTS IN THE UNITED STATES

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* Potential conflict of interest may exist. Refer to the abstract.

BACKGROUND

- Acromegaly, a rare, slowly progressing disorder resulting from excessive growth hormone (GH), is associated with a variety of complications, including cardiovascular disease, reproductive disorders, and arthropathy.[1,2]
- Delayed treatment can lead to worsening of these complications.
- The frequency of complications and treatment in the general acromegaly population is largely unknown.

OBJECTIVE

- To describe the prevalence of complications and a variety of treatments in acromegaly patients.

METHODS

Study Design and Data Source

This was a retrospective cohort study combining 2 commercial, HIPAA-compliant U.S. claims databases, Thomson Reuters MarketScan and IMS Health PharMetrics. Data covered 1/1/2002-12/31/2008 for PharMetrics and 1/1/2002-12/31/2009 for MarketScan.

Study Population and Study Timeframe

Each acromegaly patient was followed for one calendar year following the first observed acromegaly diagnosis (See diagram).

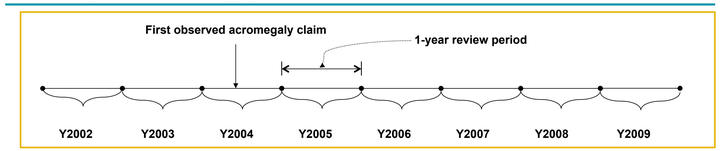
Inclusion Criteria:

- 1 medical claim with acromegaly diagnosis (ICD-9-CM code 253.0) in any diagnosis field at any time in 1/1/2002-12/31/2007 (PharMetrics) or 1/1/2002-12/31/2008 (MarketScan), and
  - either an additional claim with acromegaly diagnosis (criteria 1), or
  - evidence of treatment (criteria 2) for acromegaly (surgery, radiation, or medications) during the review period.

Exclusion Criteria:

- Patients who were not continuously enrolled in the review period.

Patients Diagnosed with Acromegaly



Measures

All pharmacy and medical claims in the review period were used to determine the following measures:

Baseline Measures: patient demographics (age, gender, region), usual care physician specialty, number of chronic conditions, and Charlson comorbidity index.[3]

Outcome Measures:

- Acromegaly treatments (surgery, radiation, and pharmacologic treatment [a]) and biochemical monitoring tests (insulin-like growth factor [IGF]-1 test, GH test).

[a] Pharmacologic treatment included octreotide long-acting release (octreotide LAR), lanreotide autogel, dopamine agonists, octreotide (short-acting [SA]), and pegvisomant.

- Six common acromegaly-related complications: colon neoplasms including polyps and cancer; musculoskeletal complications; cardiovascular disease; sleep apnea; reproductive system abnormalities; and hypopituitarism. [a]

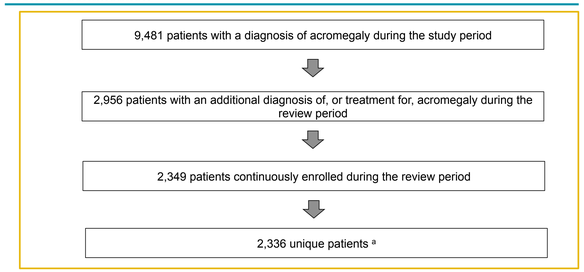
[a] Musculoskeletal abnormalities included osteoarthritis, arthropathy/arthralgia/synovitis, carpal tunnel syndrome, and hyperhidrosis; cardiovascular disease included cardiomyopathy, cardiac hypertrophy, heart failure, and cardiac dysrhythmia/arrhythmia; reproductive system abnormalities included galactorrhea, menstrual abnormality, impaired libido/impotence, and infertility.

Statistical Analyses

- Descriptive statistics, including mean, median, standard deviation, and percentage, were reported for all study measures, whenever applicable.
- All data transformations and statistical analyses were performed using SAS® version 9.2 (SAS Institute, Cary, NC).

RESULTS

Cohort Identification



[a] 13 patients were assumed to be identified from both databases, and were randomly removed from one of the databases (7 removed from PharMetrics and 6 removed from MarketScan).

- Among 2,336 identified acromegaly patients, 2,045 (87.5%) had ≥2 claims with acromegaly diagnosis (criteria 1), 1,019 (43.6%) had ≥1 claims with acromegaly diagnosis and evidence of acromegaly treatment (criteria 2), and 728 (31.2%) met both criteria in the review period.

Demographic and Clinical Characteristics

- Mean age was 45.3 years (standard deviation [SD]: 15.7) and 50.9% were female.
- 27.7% were from the Midwest, 18.0% were from the Northeast, 40.8% were from the South, and 13.5% were from the West.
- Usual care physician specialty was primary care in 34.5% of patients, endocrinology in 22.7%, cardiology in 3%, and other/unknown in 39.8%.
- Patients had a mean of 3.2 chronic conditions (SD: 1.8) and mean Charlson comorbidity index of 1.0 (SD: 1.8).

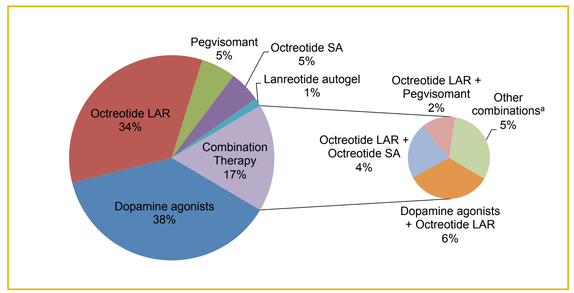
Acromegaly Monitoring and Treatment (N=2,336)

	No.	%
Any biochemical monitoring test	1,234	52.8
Any IGF-1 test	1,189	50.9
Any GH test	700	30.0
Acromegaly treatment received [a]		
Surgery	121	5.2
Radiation	57	2.4
Pharmacologic treatment [b]	914	39.1

[a] Patients could have more than one type of treatment.
[b] Included octreotide LAR, lanreotide autogel, dopamine agonists, octreotide SA, and pegvisomant.

- During the study period, 5.2% (121) had surgery, 2.4% (57) received radiation therapy, and pharmacologic treatment was used by 39.1% (914). The majority of patients were likely to have had surgery or radiation before the study period.
- 53%(1,234) of patients had at least one biochemical monitoring test (either IGF-1 or GH) during the year: 50.9% (1,189) of patients had IGF-1 and 30% (700) had GH test in that time period.

Pharmacologic Treatment in Acromegaly Patients (N=914)



[a] Includes all other combinations, with each individual combination used by <1% of patients who received pharmacologic treatment (N=914).

- Among 914 patients treated with pharmacologic therapies, 38% used dopamine agonists, 34% octreotide LAR, 5% octreotide SA, 5% pegvisomant, and 1% lanreotide autogel. 17% used more than one of these agents during the observation period.

Acromegaly-Related Complications (N=2,336)

	No.	%
Colon Neoplasm	147	6.3
Polyp	132	5.7
cancer	22	0.9
Cardiovascular disease	227	9.7
Reproductive system abnormality	251	10.7
Sleep apnea	259	11.1
Hypopituitarism	352	15.1
Musculoskeletal	586	25.1

- The most common complications were musculoskeletal abnormalities: 25.1%; hypopituitarism: 15.1%; and sleep apnea: 11.1%.

LIMITATIONS

- This study provided an initial evaluation of a possible case-finding algorithm for acromegaly using a large merged claims database (MarketScan and PharMetrics). Further review and analyses of this algorithm are needed, followed by validation in medical charts.
- Some of the patients in this study may not have required acromegaly-related treatment if they had a surgical cure or entered remission prior to the observation period of this study.
- Only treatment in the study year was examined, and many patients would have had surgery or radiation in years prior to the study.
- The lack of historical data extended before the study year makes it impossible to assess treatment patterns over time.
- The study population was a sample of commercially insured patients, which may not be generalizable to a non-managed care national population.

CONCLUSIONS

- **Pharmacologic treatment is common, with octreotide and dopamine agonists used most frequently.**
- **Medical complications of acromegaly, including musculoskeletal abnormalities, hypopituitarism, sleep apnea, and reproductive system abnormalities are common.**
- **Several key complications of acromegaly have been shown in other research to be reversible with treatment. [4]**
- **Appropriate attention to these complications along with adequate therapy and monitoring are critical in the approach to this disease.**

References

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