Management of Gout in the United States: A Claims-based Analysis

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Objective. Gout is the most common inflammatory arthritis in the United States. Although numerous guidelines exist for the management of gout, they are not routinely implemented. This study evaluated the real-world practice patterns in gout patients using large administrative claims databases.

Methods. An analysis of patients diagnosed with gout from October 2015 to November 2018 was carried out using the Symphony Integrated Dataverse and Truven Marketscan administrative claims databases. Patients were identified as having gout if they were more than 18 years of age and had 2 or more primary gout diagnoses on different days, separated by 3 or more months. Patients were further identified as having either acute gout or advanced forms of gout including chronic nontophaceous, tophaceous, and uncontrolled gout. Percent and frequency of serum urate testing, rheumatology specialist visits, prescriptions for urate lowering therapies (ULTs), and emergency room (ER) visits for gout flares were evaluated.

Results. We identified 1,162,747 gout patients. Gout patients were seen most frequently by internists and family medicine practitioners. Neither urate testing nor prescriptions for ULTs were uniform. Patients with acute gout were infrequently seen by rheumatologists, whereas rheumatologist care progressively increased in patients with advanced gout. The frequency of serum urate testing and prescriptions for ULTs significantly increased, whereas the frequency of ER visits decreased in gout patients seen by a rheumatologist.

Conclusion. Measurement of serum urate and prescriptions for ULTs are not consistent in gout patients. Rheumatologist care increases the frequency of urate measurement and ULT prescriptions and may also improve outcomes for gout patients.

INTRODUCTION

Gout is a common inflammatory arthropathy characterized by hyperuricemia and recurrent arthritis flares caused by monosodium urate (MSU) crystal deposition. Despite available urate lowering therapies (ULTs), many patients progress to advanced gout, which is characterized by the development of tophi, chronic arthritis, and other manifestations resulting from persistent urate deposition (1). Although numerous evidence-based guidelines exist for the management of gout, most information indicates that these guidelines are not routinely implemented. However, there is little information on the frequency of their implementation in real-world experience, especially in patients with advanced gout.

Evidence-based guidelines published by rheumatology societies recommend monitoring of serum urate and treatment with ULTs to lower levels of serum urate and reduce the burden of advanced gout. The American College of Rheumatology (ACR), European League Against Rheumatism (EULAR), and 3e (Evidence, Expertise, Exchange) Initiative all recommend routine serum urate measurements with a ULT treat-to-target approach aimed at lowering serum urate levels to below the saturation threshold at which MSU crystals form in the joints (2–5). The American College of Physicians (ACP), which primarily represents the primary care point of view, recently published guidelines that differ substantially from those of numerous international rheumatology societies. The ACP guidelines promote a “treat-to-avoid-symptoms” manage-
Many patients with gout are not being cared for according to American College of Rheumatology (ACR), European League Against Rheumatism (EULAR), and 3e (Evidence, Expertise, Exchange) Initiative guidelines established by the rheumatology community.

Even in patients diagnosed with advanced forms of gout, serum urate testing, rheumatology consults, and urate-lowering therapy prescriptions are lower than expected.

Patients seen by a rheumatologist at least once had a significantly increased adherence to ACR/EULAR/e3 clinical guidelines, including serum urate testing and urate-lowering therapy recommendations.

Moreover, patients seen by a rheumatologist at least once had a significantly decreased frequency of emergency room visits for gout flares.

**SIGNIFICANCE & INNOVATIONS**

- Many patients with gout are not being cared for according to American College of Rheumatology (ACR), European League Against Rheumatism (EULAR), and 3e (Evidence, Expertise, Exchange) Initiative guidelines established by the rheumatology community.
- Even in patients diagnosed with advanced forms of gout, serum urate testing, rheumatology consults, and urate-lowering therapy prescriptions are lower than expected.
- Patients seen by a rheumatologist at least once had a significantly increased adherence to ACR/EULAR/e3 clinical guidelines, including serum urate testing and urate-lowering therapy recommendations.
- Moreover, patients seen by a rheumatologist at least once had a significantly decreased frequency of emergency room visits for gout flares.
Clinical management with or without rheumatology visit. Patients were stratified based on whether they had at least one rheumatology specialist claim in their database history or no rheumatology claims. The percentage of patients with serum urate tests and ULT prescriptions was calculated and compared between groups. The frequency of serum urate tests (mean tests/year) and the number of ULT prescriptions (mean prescriptions/year) were also calculated as described above and compared between groups. The number of ER visits was also compared between the two groups.

ER presentations with or without rheumatology visit. Patients were stratified based on whether they had at least one rheumatology specialist claim in their database history or no rheumatology claims. The percentage of patients with at least one documented ER presentation with gout being the primary diagnosis was calculated and compared between groups. The mean number of ER visits per patient over the 3-year study period was also calculated and compared between groups.

Statistical analysis. Formal comparisons were performed between 1) patients with acute gout and each advanced gout category as well as 2) between patients in each category with and without at least one rheumatology visit. All statistical analyses for measurements of the percentage of patients were carried out with a two-proportion z-test. For statistical analysis of annual frequency measurements, a one-sided Welch $t$-test was used. Values of $P < 0.05$ were considered statistically significant.

RESULTS

Gout categories and etiologies. We identified 987,127 acute gout patients and 175,620 advanced gout patients. Of the 175,620 advanced gout patients, 122,162 were categorized as nontophaceous chronic, 27,769 as tophaceous chronic, and 25,689 as uncontrolled gout. The most common etiology for acute gout patients was unspecified, whereas idiopathic and secondary causes of gout were less common. For all categories of advanced gout, codes for both idiopathic and unspecified gout were found in the majority of patient claims histories. The large majority (more than 75%) of patients in all categories had at least 1 year of claims data before and following the date of their first gout diagnosis. These results are summarized in Table 1.

Patient characteristics. Table 2 summarizes the demographic and clinical characteristics for the patient populations. The mean age was more than 60 years with a strong male predominance for all gout categories. Supplementary Figure 1 depicts the distribution of patient ages within each gout category relative to the US census population estimates. The average years of claims history in the database was more than 5 years for all categories, and more than 93% of patients in each category had prescription
drug claims data available. There was little difference in comorbidities between gout categories, with hypertension and hyperlipidemia being the most common. The most common physician specialties coding for the gout diagnosis were internal medicine, family medicine, emergency medicine, nephrology, and rheumatology (Figure 1). Acute gout was most commonly diagnosed by internal medicine or family medicine physicians. Rheumatologists were far more likely to code for tophaceous chronic or uncontrolled gout than other gout categories.

**Patient management.** The percentage of patients in each category with claims for serum urate testing, rheumatology specialist visits, and prescriptions for ULTs, as well as the annual frequency of these claims are shown in Table 3. As expected, these claims were least common and infrequent in patients with acute gout. However, even in patients diagnosed with chronic or uncontrolled gout, the frequencies of serum urate testing, rheumatology consults, and ULT prescriptions were inconsistent. Serum urate testing was definitive for uncontrolled gout patients but was performed in less than 70% of patients with the diagnosis of chronic gout. For acute gout, serum urate testing was performed in less than 60% of patients. Serum urate testing was performed approximately once a year for patients with tophaceous chronic gout and less than once per year for those with acute or nontophaceous chronic gout. Patients with acute gout were infrequently seen by rheumatologists. The likelihood of encountering a rheumatologist progressively increased in subjects with advanced gout. However, nontophaceous chronic gout patients were less likely to be seen by a rheumatologist than patients with tophaceous or uncontrolled gout. Overall, less than 60% of patients with advanced gout received care by a rheumatologist, whereas less than 30% of patients with nontophaceous chronic gout were seen by a rheumatologist. For patients with acute gout, less than 15% had a documented rheumatologist visit. With regard to ULTs, less than 80% of advanced gout patients received ULT and for less than 50% of the year. The percentage of patients on ULT and the frequency of ULT prescriptions were somewhat lower for the acute gout population.

**Comparison of patient management with and without a rheumatologist visit.** Significant differences in gout management were observed between patients who had visited a rheumatology specialist compared with those who had not. Again, serum urate testing was definitive for uncontrolled gout, but for acute and chronic gout, a significantly greater percentage of patients received serum urate testing if they had seen a rheumatologist at least once during the study period. For all categories of acute and advanced gout, the percentage of patients and annual frequency of ULT prescriptions were also significantly higher for patients who had received care by a rheumatologist compared with those who had never visited a rheumatologist. These results are summarized in Table 4.

**Comparison of ER visits in gout patients with and without a rheumatologist visit.** To determine the effect of rheumatology specialist care on health outcomes, we evaluated the frequency of ER visits for patients with gout, with or
without a history of a rheumatologist visit. To accomplish this, we applied the same patient inclusion criteria to the Truven database, which also includes data on adjudicated claims for ER visits. We identified 284,877 total gout patients in Truven. The median age was 59.2 years, and 79.0% were male. Of the 230,698 subjects coded as acute gout, 10.7% were seen by a rheumatologist, whereas 26.9% of the 32,942 patients coded as nontophaceous chronic, 47.2% of the 7,723 coded as tophaceous chronic, and 43.5% of the 13,514 coded as uncontrolled gout were seen by a rheumatologist. In each gout category, the frequency of ER visits was significantly ($P < 0.001$) reduced in patients who had been seen by a rheumatologist (Table 5). The mean number of ER visits per patient was also significantly reduced in all categories of gout patients who had been seen by a rheumatologist. If the frequencies of rheumatologist-associated gout patient ER visits were applied to all gout patients, there would have been 3088 fewer ER visits in this cohort of 284,877 gout patients.

Figure 1. Distribution of percentage of gout categories diagnosed by each of the top five most common medical specialties to diagnoses gout in this study.

Table 3. Percentages and annual frequencies of uric acid testing, rheumatology visits, and serum urate-lowering therapies

| Population | N       | Serum Urate Testing (% of patients)$^b$ | Rheumatology Visits (% of patients)$^b$ | ULTs (% of patients)$^b$ |
|------------|---------|----------------------------------------|----------------------------------------|-------------------------|
| Acute gout | 987,127 | 55.22%                                 | 14.35%                                 | 64.07%                  |
| Nontophaceous chronic gout | 122,162 | 62.8% ($P < 0.001$) | 27.7% ($P < 0.001$) | 76.8% ($P < 0.001$) |
| Tophaceous chronic gout | 27,769  | 67.7% ($P < 0.001$) | 56.1% ($P < 0.001$) | 77.8% ($P < 0.001$) |
| Uncontrolled gout | 25,689 | 100% ($P < 0.001$)$^c$ | 52.4% ($P < 0.001$) | 78.6% ($P < 0.001$) |

| Population | Mean Urate Tests per Year | Mean Rheumatology Visits per Year | Mean ULT Prescriptions per Patient | Mean Days with Active ULT Prescription per Year |
|------------|---------------------------|-----------------------------------|-----------------------------------|-----------------------------------------------|
| Acute gout | 0.57                      | 0.50                              | 4.40                              | 115.96                                       |
| Nontophaceous chronic gout | 0.69 ($P < 0.001$) | 1.53 ($P < 0.001$) | 5.5 ($P < 0.001$) | 159.9 ($P < 0.001$) |
| Tophaceous chronic gout | 1.09 ($P < 0.001$) | 3.59 ($P < 0.001$) | 6.2 ($P < 0.001$) | 159.8 ($P < 0.001$) |
| Uncontrolled gout | 3.15 ($P < 0.001$) | 3.54 ($P < 0.001$) | 7.0 ($P < 0.001$) | 162.5 ($P < 0.001$) |

Abbreviation: ULT, urate-lowering therapy.
$^a$Analysis performed on data from Symphony Integrated Dataverse population.
$^b$P values reported reflect comparisons to urate testing, rheumatology visits, and serum urate-lowering therapies in acute gout.
$^c$Definitional.
DISCUSSION

Over a 3-year study period, we identified nearly 1 million gout patients in the United States, with more than 175,000 having an advanced form of the disease. A large majority of patients in the Symphony population had several years of longitudinal data in their treatment history. We found that many patients with gout were not being cared for according to the guidelines promulgated by the rheumatology community. Even in patients diagnosed with advanced forms of gout, serum urate testing, rheumatology consults, and ULT prescriptions were inconsistent. However, patients seen by a rheumatologist at least once had a significantly increased adherence to ACR/EULAR/e3 clinical guidelines and a significantly decreased frequency of ER visits for gout flares. Strategies for appropriate and timely referral to a rheumatologist would seem to be important for improving the outcomes of patients with gout.

Our findings imply that many gout patients are not receiving the management recommended in the majority of published gout management guidelines to prevent irreversible consequences of advanced disease. Specifically, serum urate testing was carried out in only 60% to 70% of patients with chronic gout with a mean number of tests per year far below the ACR recommendation for measurements every 6 months once target serum urate levels are achieved (2). Patients categorized as having uncontrolled gout had

Table 4. Comparison of patient management with or without history of rheumatology visit

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|---|---|---|
| | Percentage of Patients with Gout Management Parameters<sup>a</sup> | Serum Urate Testing | ULT |
| Population | With Rheumatology Visit(s) | No Rheumatology Visit(s) | P Value | With Rheumatology Visit(s) | No Rheumatology Visit(s) | P Value |
| Acute gout | 62.5% (n = 141,664) | 54.0% (n = 845,463) | <0.001 | 74.5% (n = 141,664) | 62.3% (n = 845,463) | <0.001 |
| Nontophaceous chronic gout | 68.9% (n = 33,894) | 60.4% (n = 88,268) | <0.001 | 82.6% (n = 33,894) | 74.5% (n = 88,268) | <0.001 |
| Tophaceous chronic gout | 73.0% (n = 15,565) | 60.9% (n = 12,204) | <0.001 | 83.4% (n = 15,565) | 70.6% (n = 12,204) | <0.001 |
| Uncontrolled gout | 100%<sup>b</sup> (n = 13,468) | 100%<sup>b</sup> (n = 12,221) | ... | 82.9% (n = 13,468) | 73.8% (n = 12,221) | <0.001 |

Table 5. Comparison of emergency room visits in patients with or without rheumatology visit

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|---|---|---|
| | Percentage of Patients with ER Visits | Mean ER Visits per Patient |
| Population | With Rheumatology Visit(s) | No Rheumatology Visit(s) | P Value | With Rheumatology Visit(s) | No Rheumatology Visit(s) | P Value |
| Acute gout | 5.6% (n = 24,638) | 6.6% (n = 206,060) | <0.001 | 1.47 (n = 24,638) | 1.53 (n = 206,060) | <0.001 |
| Nontophaceous chronic gout | 5.5% (n = 88,663) | 6.6% (n = 24,079) | <0.001 | 1.95 (n = 88,663) | 2.39 (n = 24,079) | <0.001 |
| Tophaceous chronic gout | 10.3% (n = 36,468) | 14.7% (n = 40,705) | <0.001 | 2.78 (n = 36,468) | 2.89 (n = 40,705) | <0.001 |
| Uncontrolled gout | 12.3% (n = 5886) | 19.0% (n = 7628) | <0.001 | 2.06 (n = 5886) | 2.56 (n = 7628) | <0.001 |

Abbreviation: ER, emergency room.
<sup>a</sup>Analysis performed on data from Truven Marketscan population.
<sup>b</sup>Definitional.

Abbreviation: ULT, urate-lowering therapy.
higher mean serum urate tests per year by definition. However, less than 80% of all advanced gout patients, including the uncontrolled category, received prescriptions for ULT, with prescriptions covering only 50% of the year. Importantly, there was a significant increase in the frequency of both serum urate testing and ULT prescriptions in all categories of acute and advanced gout when a patient had a history of at least one rheumatology specialist visit.

There is disagreement between rheumatology and primary care physician societies with regard to gout management (6). Recently, the ACP presented a clinical practice guideline for the management of gout that differs substantially from all others developed by American and international rheumatologists (7). Specifically, the ACP guidelines do not offer clear recommendations for ULT, serum urate target levels, or routine serum urate monitoring. Our results appear to support the conclusion that primary care providers’ approach to gout is more in line with the ACP guidelines than those of rheumatologists, whereas rheumatologists’ practice is more in line with the sub-specialty guidelines. Although cause and effect cannot be established, the data suggest that involvement of a rheumatologist results in a reduction in ER visits, implying that more frequent monitoring and better ULT management may have a positive impact on gout patients’ ER utilization, a surrogate for better health outcome.

Strengths of our study include the large number of patients and use of administrative claims. Therefore, every instance of gout diagnosis was based on a claim confirmed by a medical provider, and ULT usage was based on filled prescriptions. Moreover, rather than treating gout as a single disease entity, we have been able to evaluate the different treatment practices in acute versus more advanced forms of gout. Using this approach, we identified significant differences in management patterns and inclusion of a rheumatologist in the management team. It is notable that the frequencies of comorbidities were not different based on the coding of acute versus chronic gout. This could relate to the difficulty of determining whether to code an acute flare as acute gout even if it occurred in a subject with longstanding gout. Consistent with this is the finding that the mean length of follow-up in the database did not differ in those coded with acute versus advanced gout. Importantly, these findings are consistent with reports that many comorbidities associate with hyperuricemia and not gout per se (17–19).

Although several large administrative claims or medical records studies of gout management have been reported in Canada, Europe, and Taiwan (15,20–22), data on United States populations are more limited. Prior large-scale studies of gout patients in the United States have relied mostly on patient self-reported gout diagnosis and ULT prescriptions, which may inflate prevalence while also underestimating ULT administration (9). However, administrative claims data in other countries have reported similar trends to those found in this study. For example, one study in Germany and the United Kingdom demonstrated that just over half of patients had received ULT treatment and only 9% to 14% of patients with gout received at least one serum urate test in the several years following diagnosis (15). ULT prescription rates were even lower in Canadian (20) and Taiwanese populations (21).

Patients in our study had demographic characteristics and comorbidities similar to those previously reported (23,24). However, we found somewhat higher rates of serum urate testing and ULT therapy compared with previous survey-based studies of gout patient medical management (9). Compared with survey-based data of providers, we also found much higher levels of ULT treatment and larger differences between rheumatology specialists compared with nonspecialists. For example, a quantitative US survey that assessed primary care provider and rheumatologist adherence to the ACR guidelines found that 53.7% of primary care providers and 35.3% of rheumatologists were poorly adherent, whereas only 36.4% and 35.2%, respectively, prescribed the recommended initial ULT dose (25).

Limitations of our study include the fact that our results were based on administrative claims and do not incorporate the full patient clinical history as well as the fact that specific gout diagnoses could not by verified by chart review. Therefore, confidence in patient gout diagnosis and categorization is less than if there were clinical confirmation based on accepted classification criteria or MSU crystal identification. Similarly, we were not able to assess the serum urate values measured to determine whether or not patients were hyperuricemic or at target levels. For ULT prescription data, because unfilled prescriptions were not counted, it is possible that we underestimates the true frequency at which providers are recommending ULT therapy for gout patients.

Recent studies have estimated that overall prevalence of gout among adults in the United States exceeds 9 million people (9). Our study identified more than 1 million patients with a gout diagnosis, indicating that the administrative claims databases may not be capturing all patients. Truven, and to a lesser extent Symphony, do not capture all Medicare and Medicaid enrollees (26). Furthermore, neither data set would capture uninsured patients or those primarily receiving care at the Veterans Health Administration. Despite the issues, there is a major discrepancy between the number of subjects identified and the number anticipated from the most recent prevalence estimate of 3.9% of adults derived from National Health and Nutrition Examination Survey data (9). Part of this could relate to the inflation of prevalence owing to the reliance on self-reporting in the aforementioned study. On the other hand, gout may be underdiagnosed in our study. Moreover, subjects with only a small number of flares may not enter the health care system. The important issue is whether the gout patients identified in our study were representative. The demographics suggest that they are typical of other cohorts of gout patients (23,27). However, it is possible that the frequencies of serum urate measurement, ULT prescriptions, and rheumatologist involvement were inflated in our study because we identified the subset of gout patients involved in the organized health care system. Future studies will be necessary to explore this issue more fully.

Together, this study provides data on real-world management of acute and advanced gout and highlights the need for increased
gout clinical management awareness and education. We found that many patients are not being managed according to ACR/EULAR guidelines and that patients seen by rheumatology specialists are more likely to receive recommended care, which may impact patient outcomes, such as frequency of ER visits. Given that most patients with acute gout are not seen by a rheumatologist and less than half of those with advanced gout encounter a rheumatologist, follow-up studies to evaluate the effect of health outcomes related to these differences will be informative. More frequent referral to rheumatologists and closer adherence to guidelines may improve outcomes for gout patients.

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AUTHOR CONTRIBUTIONS
All authors reviewed and revised the manuscript and approved of its submission.

Study conception and design. Edwards, Schlesinger, Lipsky.

Acquisition of data. Clark, Arndt.

Analysis and interpretation of data. Clark, Arndt, Lipsky.

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