Evaluation of real-world treatment patterns in patients with uncontrolled gout in the USA

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BACKGROUND

- Gout is a common inflammatory rheumatic disease caused by deposition in joints of monosodium urate crystals resulting from elevated or excess serum uric acid (sUA) levels.[1]
- Guidelines for gout management recommend targeting sUA levels below 6 mg/dL as a sustained reduction of sUA concentrations allows for dissolution of monosodium urate crystals, reduced gout flares and resolution of tophi.[1–3]
- Ongoing clinical manifestations and failure to reduce sUA levels below 6 mg/dL, known as uncontrolled gout, can occur despite the use of urate-lowering therapies (ULTs).[1,4]
  - Uncontrolled gout may occur due to a failure to reduce sUA levels at the maximum therapeutic dose of ULTs; poor responses to ULTs may be due to intolerance, non-compliance, and delayed prescribing.[1,4]
  - Failure to adequately control sUA is indicative of poor prognosis in patients with gout.[4]
- As there is limited real-world evidence on the treatment patterns of patients with uncontrolled gout, our study aimed to assess the treatment patterns associated with management of uncontrolled gout, defined by elevated sUA levels at baseline, among US patients treated in routine clinical practice.

METHODS

- This study was a retrospective analysis of a US health plan claims database (IQVIA PharMetrics® Plus).
- Adult patients (≥18 years) considered to have uncontrolled gout based on prescription data (at least three flares within 18 months or at least one pegloticase prescription following gout diagnosis) were identified between June 2011 and May 2020. Flares were defined by a medical claim with gout diagnosis followed by at least one prescription of colchicine, corticotropin, prescription non-steroidal anti-inflammatory drugs (NSAIDs), or steroids within 7 days.
- Patient data were collected from 6 months before (i.e. baseline period) to 12 months after (i.e. follow-up period) the index date (first of either the date of the third prescription of therapy used to manage flares, or the date of the first prescription of pegloticase).
- The study further identified a subpopulation with uncontrolled sUA levels during the baseline period (a reported sUA level ≥6.0 mg/dL), where data were available.
- Demographics, clinical characteristics, and treatment patterns were examined, and are presented here for the subpopulation of patients with uncontrolled sUA levels during the baseline period.

RESULTS

Demographics and clinical characteristics during baseline

- A total of 95,369 patients were considered to have uncontrolled gout based on prescription data.
- Of the 1,289 patients with reported sUA levels during baseline, 969 patients had uncontrolled sUA levels during this period.
- For the 969 patients with uncontrolled sUA levels during baseline:
  - The median age was 54.7 years (**Table 1**).
  - Median (range) time from first observed diagnosis of gout to index date was 274.0 days (3.0–3,214.0).
  - Charlson comorbidity index mean ± standard deviation (SD) was 0.7 ± 1.3.
  - Common comorbidities included hypertension (59.1%), joint pain (40.8%), dyslipidemia (34.9%), obesity (20.5%), type 2 diabetes (16.6%), and renal disease (15.0%) (**Figure 1**).
  - Tophi were reported in 50 (5.2%) patients.

Table 1. Demographics and clinical characteristics of patients with uncontrolled sUA levels during baseline*†

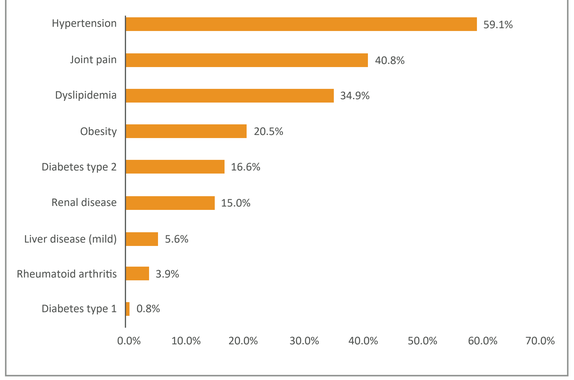
Characteristics	Patients with uncontrolled sUA during baseline* (N=969)
Age at index date,† years	
Mean ± SD	53.8 ± 10.9
Median (IQR)	54.7 (47.2–61.2)
Range	21.7–83.4
Unknown	32 (3.3%)
Age categories at index date,† n (%)	
18–39 years	114 (11.8%)
40–54 years	372 (38.4%)
55–64 years	336 (34.7%)
65–74 years	92 (9.5%)
75–84 years	23 (2.4%)
Unknown	32 (3.3%)
Sex, n (%)	
Female	124 (12.8%)
Male	845 (87.2%)
Geographic region of the USA, n (%)	
South	368 (38.0%)
Midwest	165 (17.0%)
Northeast	288 (29.7%)
West	147 (15.2%)
Unknown	1 (0.1%)
Time from first observed diagnosis of gout to index date, days	
Mean ± SD	477.7 ± 554.4
Median (IQR)	274.0 (109.0–597.0)
Range	3.0–3,214.0

*Patients with uncontrolled sUA levels included those whose sUA level closest to the index date was ≥6.0 mg/dL during the baseline period or at the index date among patients with available lab data

†To comply with the Health Insurance Portability and Accountability Act (HIPAA), year of birth is missing for patients over 85 years old in the data. These patients were classified as age 'unknown' in this analysis. The mean age summarized in the table is likely an underestimate since patients older than 85 are not included in the estimate

IQR, interquartile range; SD, standard deviation; sUA, serum uric acid

Figure 1. Percentage of patients with comorbidities during baseline (N=969)



Treatment patterns

- Patients with uncontrolled sUA levels during baseline received a median (range) of 2.0 (0.0–5.0) treatments during the follow-up period.
  - 70.5% and 11.8% of patients received the xanthine oxidase inhibitors allopurinol and febuxostat, respectively; 0.9% of patients received pegloticase; 77.0% of patients received steroids; and 59.3% of patients received NSAIDs (**Table 2**).
  - The number of prescriptions are shown in **Table 2**.

sUA, flares, and serum creatinine levels during the follow-up period

- For the 969 patients with uncontrolled sUA levels during baseline:
  - The mean ± SD number of flares was 1.3 ± 1.8.
  - Mean ± SD serum creatinine level during follow-up was 1.2 ± 0.6.
  - 490 (50.6%) had at least two reported sUA results during follow-up, of which 280 (57.1%) did not achieve control of their sUA level (at least one sUA <6.0 mg/dL) at any point during follow-up.

CONCLUSION

- In these real-world data, sUA levels remained elevated in more than half of the patients with uncontrolled gout during the follow-up period despite treatment use.
- There remains a high unmet need for new effective treatment and improved management of patients with uncontrolled gout.

Table 2. Gout-related treatment patterns during the follow-up period*

Treatment	Patients with uncontrolled sUA levels during baseline (N=969)*
Number of gout-related treatments,† n (%)	
0	13 (1.3%)
1	151 (15.6%)
2	440 (45.4%)
3	330 (34.1%)
4+	35 (3.6%)
Mean ± SD	2.2 ± 0.8
Median (IQR)	2.0 (2.0–3.0)
Range	0.0–5.0
Number of prescriptions during follow-up period‡	
Pegloticase, n (%)	9 (0.9%)
Mean ± SD	8.7 ± 7.2
Median (IQR)	7.0 (3.0–12.0)
Range	2.0–25.0
Xanthine oxidase inhibitors	
Allopurinol, n (%)	683 (70.5%)
Mean ± SD	6.0 ± 3.9
Median (IQR)	5.0 (3.0–9.0)
Range	1.0–28.0
Febuxostat, n (%)	114 (11.8%)
Mean ± SD	6.1 ± 3.8
Median (IQR)	5.0 (3.0–9.0)
Range	1.0–15.0
NSAIDs, n (%)	575 (59.3%)
Mean ± SD	3.5 ± 3.2
Median (IQR)	2.0 (1.0–5.0)
Range	1.0–19.0
Steroids, n (%)	746 (77.0%)
Mean ± SD	3.9 ± 3.8
Median (IQR)	3.0 (1.0–5.0)
Range	1.0–31.0
Uricosuric agents	
Probenecid, n (%)	32 (3.3%)
Mean ± SD	4.3 ± 3.6
Median (IQR)	3.0 (1.0–6.5)
Range	1.0–13.0
Lesinurad, n (%)	3 (0.3%)
Mean ± SD	3.0 ± 1.7
Median (IQR)	4.0 (1.0–4.0)
Range	1.0–4.0

*Patients with uncontrolled sUA levels included those whose sUA level closest to the index date was ≥6.0 mg/dL during the baseline period or at the index date among patients with available lab data

†Gout-related treatments assessed included: pegloticase, allopurinol, febuxostat, probenecid, lesinurad, rasburicase, any prescription NSAIDs, any steroids

‡Number of prescriptions were calculated as the total number of medical and pharmacy claims associated with the treatment

IQR, interquartile range; NSAID, non-steroidal anti-inflammatory drug; SD, standard deviation; sUA, serum uric acid

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