

Burden of disease in patients with uncontrolled gout in the USA

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BACKGROUND

- Gout is among the most common of inflammatory rheumatic diseases, with increasing prevalence and incidence in developed countries, and is caused by the deposition of monosodium urate crystals in and around joints.^{1,2}
- Maintaining serum uric acid (sUA) levels below 6 mg/dL is critical in the long-term management of gout, resulting in reduced acute inflammatory responses known as gout flares that are associated with severe joint pain, swelling, and tenderness.¹
- The two defining features of uncontrolled gout are a failure to reduce sUA below 6 mg/dL and ongoing clinical manifestations.³
- Patients with gout have been observed to have impaired health-related quality of life and functional ability,⁴ and comorbidities that impose challenges on the management of gout are common.⁵
- As limited real-world evidence exists on the healthcare burden of patients with uncontrolled gout, this study aimed to assess the burden of uncontrolled gout, defined by elevated sUA levels at baseline and follow-up, among US patients treated in routine clinical practice.

METHODS

- This retrospective study firstly identified adult patients 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) between June 2011 and May 2020 from a US health plan claims database (IQVIA PharMetrics® Plus). 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.
- Where data were available, the study then identified a subpopulation who had uncontrolled gout during baseline (6 months before index date) and follow-up periods (12 months after index date) based on sUA levels (a reported sUA level ≥ 6.0 mg/dL during baseline and at least two sUA results ≥ 6.0 mg/dL during follow-up), where the index date was the first of either the date of the third prescription of therapy used to manage flares, or the date of the first prescription of pegloticase.
- Demographics, clinical characteristics, and gout-related healthcare resource use (defined as medical claims with an associated diagnostic code of gout) were examined and are presented here for patients with uncontrolled sUA levels during baseline and follow-up.

RESULTS

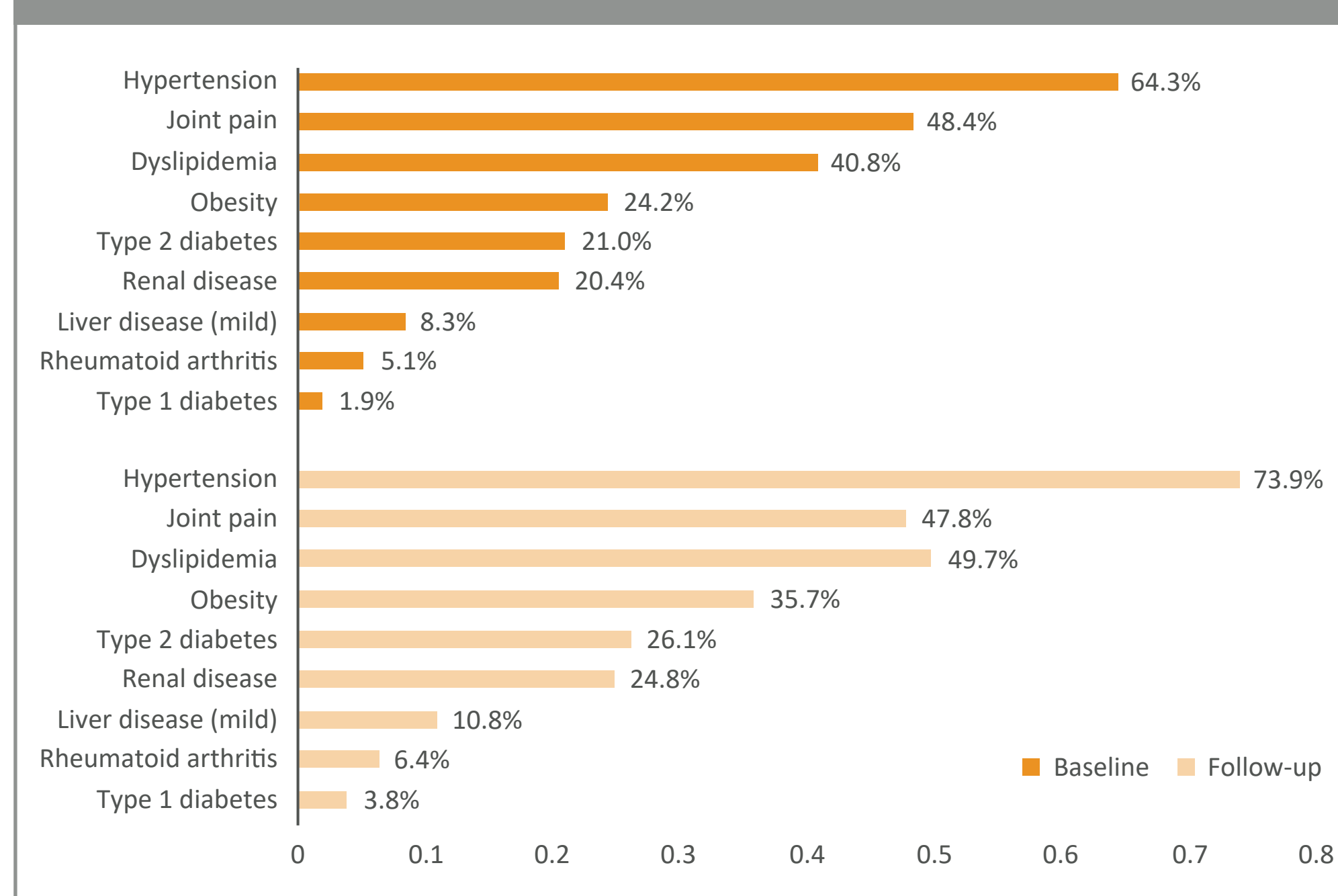
Demographics

- The overall study criteria identified 95,369 patients considered to have uncontrolled gout based on prescription data.
- Of these, 969 patients had a reported sUA level ≥ 6.0 mg/dL during baseline and 157 of these patients additionally had at least two sUA results ≥ 6.0 mg/dL during follow-up.
- For the 157 patients with uncontrolled sUA levels during baseline and follow-up:
 - 85.4% were male (Table 1).
 - Median age was 56.1 years.
 - Median time from index date to first and last sUA test during follow-up was 57 days and 263 days, respectively.

Clinical characteristics during baseline and follow-up

- Of the 157 patients with uncontrolled sUA levels during baseline and follow-up, the Charlson comorbidity index mean \pm standard deviation (SD) was 0.9 ± 1.5 during baseline and 1.3 ± 1.7 during follow-up.
 - The prevalence of common comorbidities during baseline was hypertension (64.3%), joint pain (48.4%), dyslipidemia (40.8%), obesity (24.2%), type 2 diabetes (21.0%), and renal disease (20.4%) (Figure 1). The proportion of patients with tophi during baseline was 4.5%.
 - The prevalence of common comorbidities during follow-up was hypertension (73.9%), joint pain (47.8%), dyslipidemia (49.7%), obesity (35.7%), type 2 diabetes (26.1%), and renal disease (24.8%) (Figure 1). The proportion of patients with tophi during follow-up was 8.9%.
- The mean (SD) serum creatinine level in these patients was 1.4 ± 1.2 mg/dL (n=137) during baseline and 1.3 ± 0.6 mg/dL (n=149) during follow-up.

Figure 1. Percentage of patients with comorbidities during baseline and follow-up (N=157)



Burden of disease

- Of the 157 patients with uncontrolled sUA levels during baseline and follow-up, ten (6.4%) experienced at least one gout-related hospitalization, with a median (interquartile range [IQR]) length of stay per admission of 6.0 days (3.0–7.7), and 24 (15.3%) patients had at least one gout-related emergency room (ER) visit(s), with a median (IQR) number of visits of 1.0 (1.0–1.5) (Table 2).

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

Characteristics	Patients with uncontrolled sUA levels during baseline and follow-up* (N=157)
Age at index date,[†] years	
Mean \pm SD	55.3 \pm 10.8
Median (IQR)	56.1 (48.5–62.9)
Range	30.4–80.9
Unknown	6 (3.8%)
Age categories at index date,[†] n (%)	
18–39 years	17 (10.8%)
40–54 years	51 (32.5%)
55–64 years	61 (38.9%)
65–74 years	17 (10.8%)
75–84 years	5 (3.2%)
Unknown	6 (3.8%)
Sex, n (%)	
Female	23 (14.6%)
Male	134 (85.4%)
Geographic region of the USA, n (%)	
South	72 (45.9%)
Midwest	21 (13.4%)
Northeast	35 (22.3%)
West	29 (18.5%)
Unknown	0 (0.0%)
Time from first observed diagnosis of gout to index date, days	
Mean \pm SD	491.1 \pm 584.4
Median (IQR)	274.0 (95.0–634.0)
Range	13.0–3,214.0

*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 and at least twice during the follow-up period 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

- All of these patients had at least one gout-related outpatient visit, with a median number (IQR) of outpatient visits of 5.0 (3.0–7.0).

CONCLUSION

- In these real-world data, approximately one in six patients with uncontrolled sUA levels during baseline and follow-up had at least one gout-related ER visit during the 12-month follow-up, and all patients made gout-related outpatient visits, with a median of five visits, demonstrating that uncontrolled gout confers a high burden on patients and the US healthcare system.
- Improvements in the treatment management and routine clinical management, i.e. sUA level monitoring, of gout are required to reduce this burden.

Table 2. Gout-related HRU in patients with uncontrolled sUA levels during baseline and follow-up*

HRU [†]	Patients with uncontrolled sUA levels during baseline and follow-up (N=157)
Inpatient	
Patients with at least one admission, n (%)	10 (6.4%)
Number of admissions[‡]	
Mean \pm SD	1.5 \pm 0.8
Median (IQR)	1.0 (1.0–2.0)
Range	1.0–3.0
Total inpatient days,[‡] days	
Mean \pm SD	8.6 \pm 6.0
Median (IQR)	8.0 (6.0–10.0)
Range	2.0–23.0
Length of stay per admission,[‡] days	
Mean \pm SD	6.0 \pm 3.3
Median (IQR)	6.0 (3.0–7.7)
Range	2.0–12.0
Emergency room	
Patients with at least one visit, n (%)	24 (15.3%)
Number of visits[§]	
Mean \pm SD	2.2 \pm 4.7
Median (IQR)	1.0 (1.0–1.5)
Range	1.0–24.0
Outpatient	
Patients with at least one visit, n (%)	157 (100.0%)
Number of visits[§]	
Mean \pm SD	5.8 \pm 3.6
Median (IQR)	5.0 (3.0–7.0)
Range	1.0–22.0

*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 and at least twice during the follow-up period among patients with available lab data

[†]Gout-related HRU was defined as medical claims with an associated diagnostic code of gout

[‡]Calculated among patients with at least one inpatient stay. If the inpatient stay started during the study period and extended past the end of the study period, the full duration of the inpatient stay was considered

[§]Calculated among patients with at least one visit

HRU, healthcare resource use; IQR, interquartile range; SD, standard deviation; sUA, serum uric acid

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