A Real-World Study on Treatment Patterns and Clinical Outcomes in Patients with Both Uncontrolled Gout and Chronic Kidney Disease

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CONCLUSION

- **Patients with uncontrolled gout (UG) and chronic kidney disease (CKD) stage ≥3a experienced a high and persistent disease burden from gout diagnosis to the most recent gout-related physician visit, despite more than 18 months of receiving urate-lowering therapy (ULT).**
- **Although efficacy and safety were common drivers of treatment choice, CKD–related contraindications and dose limitations, along with formulary restrictions, constrained available treatment options.**
- **Collectively, these findings suggest suboptimal treatment response to current therapies and highlight the need for treatment escalation and expanded therapeutic options for patients with uncontrolled gout and CKD stage ≥3a.**

INTRODUCTION

- Gout and CKD frequently co-occur, with approximately 25% of patients with gout also presenting with CKD. Further, gout is associated with more than a twofold increased risk of developing stage 3 CKD.[1]
- Patients with UG are approximately twice as likely to develop CKD compared with those with controlled disease, while those with more advanced CKD (stage ≥3a) have a higher risk of gout progression and tophi development.[2]
- The use of ULT to manage UG in patients with CKD is limited, generally due to concerns about lack of efficacy, potential for increased cardiovascular risks, medication interactions or non-adherence.[3-6]
- The aim of this real-world study was to evaluate gout-related treatment patterns and clinical outcomes in patients with UG and CKD stage ≥3a in a clinical practice setting.

METHODS

- Data were extracted from the Adelphi Real World Gout Disease Specific Programme™, a cross-sectional survey with retrospective data collection from physicians and patients with gout in the United States between August 2023 and March 2024.
- The DSP methodology has been previously described,[7,8] validated,[9] and demonstrated to be representative and consistent over time.[10]
- Participating rheumatologists, nephrologists and primary care physicians (PCP) managed ≥8 gout patients monthly.
- Patients with UG were defined as having serum urate (SU) >6mg/dl, as well as ≥1 of the following gout symptoms: gouty arthropathy, ≥1 tophi, or ≥2 flares in the previous year. Patients were included in this analysis if they had UG and CKD stage ≥3a (estimated Glomerular Filtration Rate (eGFR) <60 mL/min/1.73m^2) at the time of most recent visit. All patients were receiving ULT at their most recent visit.
- Descriptive analyses assessed physician-reported patient demographics, treatment patterns, and clinical outcomes across multiple time points.

RESULTS

Patient demographics and clinical characteristics

- Overall, 23 rheumatologists, 18 nephrologists and 9 PCPs provided data for 146 patients with UG and CKD stage ≥3a.
- Mean (standard deviation; SD) patient age was 61.8 (12.6) years, 81% of patients were male, and 36% were Black or African American/African or Caribbean **(Table 1)**.

Table 1: Physician-reported patient demographics and clinical characteristics at most recent visit

	Patients with UG and CKD (n=146)
Patient demographics	
Age, mean (SD), years	61.8 (12.6)
Sex, n (%)	
Male	118 (81)
Female	28 (19)
Race, n (%)	
White	81 (55)
Black or African American/African or Caribbean	53 (36)
Other[a]	18 (12)
BMI, mean (SD), kg/m^2	29.1 (5.2)
Patient clinical characteristics	
Most common comorbidities, n (%)	
Renal disease	146 (100)
Hypertension (≥140/90 mmHg)	107 (73)
Hyperlipidemia	65 (45)
Diabetes	57 (39)
Obesity	53 (36)
CVD	41 (28)
Charlson Comorbidity Index, mean (SD)	2.1 (1.5)
CKD stage, n (%)	
Stage 3a	62 (42)
Stage 3b	63 (43)
Stage 4	20 (14)
Stage 5	1 (1)

Abbreviations: BMI - Body Mass Index; CKD - chronic kidney disease; CVD - cardiovascular disease; kg - kilograms; m^2 – meters squared; mmHg - millimetres of mercury; SD - standard deviation.
[a]Other ethnicities included American Indian, Indigenous American, or Alaska Native, South or Central American Native, East or Southeast Asian, South Asian, Middle Eastern or North African, Native Hawaiian or Pacific Islander, and Other. Comorbidities present at diagnosis were not mutually exclusive. Diabetes included diabetes with chronic complications and diabetes without chronic complications. CVD included myocardial infarction, congestive heart failure, peripheral vascular disease and cerebrovascular disease. The Charlson Comorbidity Index (0-37) predicts ten-year mortality by evaluating 19 medical conditions including myocardial infarction, renal disease, malignancies and AIDs, with different conditions weighted differently based on potential influence on mortality. The score is then adjusted by patient age. The higher the score, the lower the predicted survival rate.

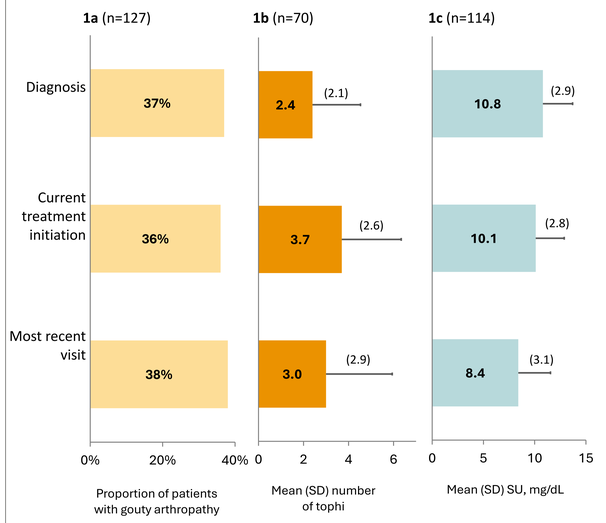
Treatment patterns and choice

- When looking at the patient journey, the mean (SD) time from gout diagnosis to initiation of the current treatment was 34.8 (66.8) months **(Figure 2a)**.
- At the time of the most recent visit, patients were prescribed a mean (SD) of 1.9 (1.1) gout medications (ULT and non-ULT), with the most commonly prescribed medications being allopurinol (62%), colchicine (31%), febuxostat (31%), and corticosteroids (27%) **(Figure 2b)**.
- Physicians commonly reported overall efficacy (84%) and safety (51%) as reasons for selecting current treatment. However, renal considerations such as “suitable for patients with renal risk/comorbidity” and “no dose limitations in CKD” were cited infrequently (14% and 13%, respectively).
- Despite these considerations, physicians indicated that CKD-related contraindications affected treatment choice in 43% of patients, while formulary restrictions prevented use of an alternative ULT in 27% of cases.

Clinical outcomes

- Despite a mean (SD) of 18.9 (21.7) months of current ULT use, patients continued to exhibit a high disease burden, including persistent gouty arthropathy, tophi, and elevated SU levels from diagnosis to the most recent visit **(Figures 2a and 1a–c)**.

Figure 1: UG clinical manifestations at the time of the most recent visit a) presence of gouty arthropathy[a], b) number of tophi, c) SU



Abbreviations: mg/dL – milligrams per decilitre; SD - standard deviation; SU - serum urate; UG – uncontrolled gout.
[a]Gouty arthropathy is defined clinically or radiographically as joint damage due to gout.
Only patients with a known answer for all time points were included.

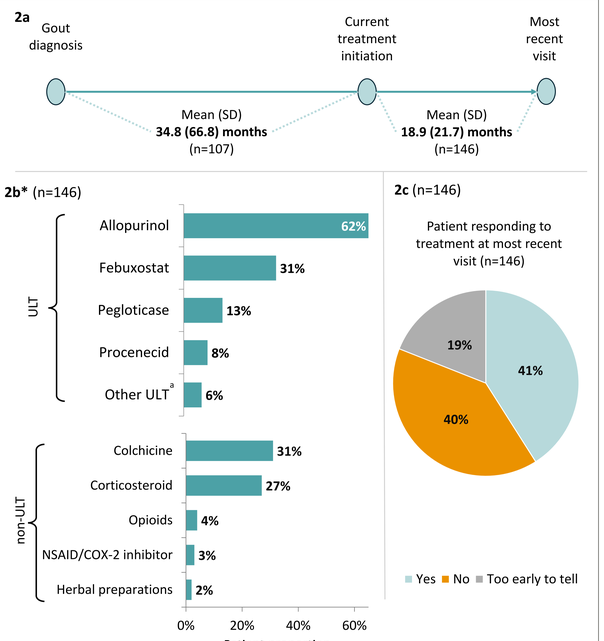
Clinical outcomes (cont.)

- Beyond elevated SU levels, tophi, and gouty arthropathy, patients also reported tender/swollen joint(s) (27%) and joint stiffness (20%) at the most recent visit.
- Additionally, in the 12 months prior to survey, patients (n=129) experienced a mean (SD) of 2.3 (1.0) gout flares.
- In contrast to the high disease burden, physicians reported that 41% of patients were responding to their current treatment **(Figure 2c)**.

LIMITATIONS

- Patients from the Adelphi Gout DSP™ did not constitute a true random sample as patients who consulted more frequently were more likely to be included in the sample; these findings may not be generalizable beyond the study population.
- Insufficient data on CKD-related biomarkers and outcomes meant that analysis of these variables together was not possible. Longitudinal data were also lacking.
- Rheumatologists, PCPs and nephrologists were recruited if they saw ≥8 patients with diagnosed gout who were receiving chronic treatment in a month, and so participating physicians were likely to be “high treaters” of gout patients.
- Electronic health records were used by physicians to complete patient characteristics and treatment history, but the information provided was not validated further.

Figure 2: Patient treatment patterns at the most recent visit, a) timeline from gout diagnosis to most recent visit, b) current treatment, and c) patient response to treatment



Abbreviations: NSAID - non-steroidal anti-inflammatory drug; COX-2 - cyclo-oxygenase-2; SD - standard deviation; ULT - urate lowering therapy.
[a]Other ULT included lesinurad, allopurinol + lesinurad, topiroxostat, dotinurad and benzbromarone.
*Multiple treatments could be selected by physicians, allowing reporting of combination treatments; therefore, the categories are not mutually exclusive.

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Disclosures

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