Comparison of Diagnostic Journey and Utilization of Clinical Care Resources in Uncontrolled vs. Controlled Gout in the United States

Jigar Shah[1], Menaka Bhor[2], James Hawthorne[2], Nathan Meyer[2], Emily J. Goddard[3], Molly Edwards[3], Alastair Hinds[3], John A. Albert[4]

Arthritis and Rheumatology Center of South Florida, Margate, FL, USA; [2]Sobi Inc, Waltham, MA, USA; [3]Adelphi Real World, Bollington, UK; [4]Rheumatic Disease Center, Glendale, WI, USA

CONCLUSION

- **Patients with uncontrolled gout (UG) experienced greater gout-related disease burden and therefore greater clinical care resource use (CCRU) compared to those with controlled gout (CG).**
- **These findings highlight the need for appropriate escalation of therapy, consistent with a treat-to-target (T2T) approach, and additional treatment options to reduce overall burden for patients with UG and the healthcare system.**

BACKGROUND

- ACR guidelines strongly recommend a T2T approach for the management of gout which uses regular serum urate (SU) monitoring to adjust urate-lowering therapy (ULT) doses to reach SU levels below 6 mg/dL, aiming to dissolve monosodium urate crystals and prevent gout flares.[1]
- Even with established ACR guidelines, [1] patients may progress to UG, defined as SU levels >6 mg/dL, with persistent clinical manifestations such as tophi, flares or gouty arthropathy, despite receiving ULTs, potentially leading to higher use of clinical care resources.
- This study aimed to compare patient profiles, diagnostic journey, and CCRU between patients with UG vs. CG in the United States (US).

METHODS

- Data were drawn from the Adelphi Real World Gout Disease Specific Programme™, a cross-sectional survey of physicians and their patients with gout in the US from August 2023 to March 2024.
- The DSP methodology has been previously described,[2,3] validated,[4] and demonstrated to be representative and consistent over time.[5]
- Participating rheumatologists, nephrologists and primary care physicians (PCPs) managed ≥8 gout patients monthly. Physicians provided data for a consecutive series of patients, who met the inclusion criteria, to reduce selection bias.
- Patients with UG were defined as SU >6mg/dl with ≥1 of the following symptoms: gouty arthropathy, ≥1 tophi, or ≥2 flares in the previous year. Patients with CG were defined as SU ≤6 mg/dL OR SU >6 mg/dL with none of the above symptoms.
- All patients were receiving ULT at the most recent visit.
- Physicians reported information on patient demographics and diagnostic journey, clinical characteristics, and gout-related CCRU (including physicians involved in patient management, hospital and other healthcare system visits, and tests used for diagnosis/monitoring).
- Unadjusted comparative analyses were performed using t-tests for continuous variables and Fisher's exact tests for categorical variables, with a two-sided significance level of $\alpha = 0.05$.

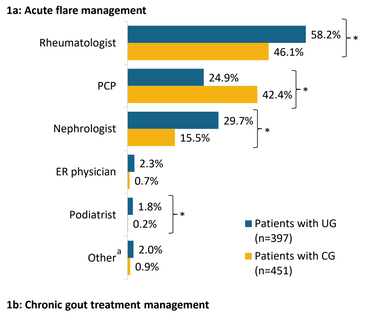
RESULTS

Table 1: Patient demographics and clinical characteristics at most recent visit

	Patients with UG (n=400)	Patients with CG (n=454)	p-value
Demographics			
Time since diagnosis, mean (SD), years	4.3 (4.9)	4.2 (4.6)	0.7613
Patient age, mean (SD), years	57.6 (12.1)	56.4 (13.2)	0.1697
Patient sex, n (%)			0.0542
Male	316 (79.0)	332 (73.3)	
Female	84 (21.0)	121 (26.7)	
Race, n (%)			
White	244 (61.0)	307 (67.6)	**0.0451**
Black or African American/African or Caribbean	113 (28.3)	88 (19.4)	**0.0027**
Other[a]	51 (12.8)	64 (14.1)	0.6158
Employment status, n (%)	n=379	n=442	**0.0035**
Working full-time	200 (52.8)	275 (62.2)	
Retired	87 (23.0)	105 (23.8)	
Working part-time	58 (15.3)	44 (10.0)	
Unemployed	20 (5.3)	11 (2.5)	
Other[b]	14 (3.7)	7 (1.6)	
Additional support/care required[c], n (%)	n=386	n=446	**0.0001**
Additional support/care required	81 (21.0)	50 (11.2)	
No additional support/care required	305 (79.0)	396 (88.8)	
Clinical characteristics at most recent visit			
SU, mean (SD), mg/dL	9.1 (4.3)	5.8 (3.5)	**<0.0001**
Number of tophi, mean (SD)	1.7 (2.6)	0.3 (1.1)	**<0.0001**
Flares in prior year, mean (SD)	n=357 2.3 (1.1)	n=429 0.8 (1.0)	**<0.0001**
Presence of gouty arthropathy[d], n (%)	135 (33.8)	29 (6.4)	**<0.0001**
Presence of tender/swollen joints, n (%)	111 (27.8)	93 (20.5)	**0.0157**
Presence of warm joints, n (%)	66 (16.5)	33 (7.3)	**<0.0001**
Presence of pain between flares, n (%)	54 (13.5)	32 (7.0)	**0.0020**
Most common comorbidities, n (%)			
Hypertension (≥140/90mmHg)	237 (59.3)	270 (59.5)	1.0000
Renal disease	181 (45.3)	139 (30.6)	**<0.0001**
Hyperlipidemia	135 (33.8)	176 (38.8)	0.1349
Obesity	139 (34.8)	151 (33.3)	0.6644
Diabetes with chronic complications	70 (17.5)	53 (11.7)	**0.0189**
Diabetes without chronic complications	55 (13.8)	52 (11.5)	0.3514
Congestive heart failure	46 (11.5)	23 (5.1)	**0.0006**
Charlson Comorbidity Index[e], mean (SD)	1.2 (1.4)	0.7 (1.1)	**<0.0001**

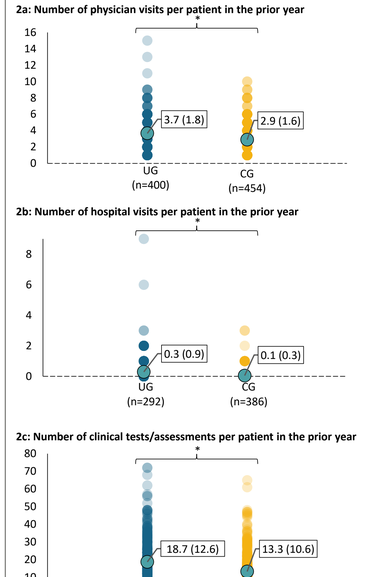
CG-controlled gout; UG-uncontrolled gout; kg-kilograms; m^2-meters squared; mmHg-millimetres of mercury; SD-standard deviation; SU-serum urate. T-tests (continuous variables) and Fisher's exact tests (categorical variables) used, with bold p-values for significant differences in characteristics between patients with UG and CG (p≤0.05). [a]Other included South or Central American Native, East or Southeast Asian, American Indian, Indigenous American, or Alaska Native, South Asian, Middle Eastern or North African, Native Hawaiian or Pacific Islander, and other. [b]Other included homemaker, on long-term sick leave and student. [c]Additional support/care required as a result of the patient's gout, beyond what would usually be expected for a person of their age. [d]Gouty arthropathy, defined clinically or radiographically as joint damage due to gout. [e]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.

Figure 1: Physician types involved in management in the prior year for patients with UG vs. patients with CG



ER-emergency room; CG-controlled gout; UG-uncontrolled gout; PCP-primary care physician. Options were not mutually exclusive.
[a]Other included nurse/nurse practitioner, orthopaedic surgeon, other physicians or other (physical therapists or chiropractors). [b]Other included nurse/nurse practitioner, podiatrist, ER physician, other physicians or other (physical therapists or chiropractors). Fisher's exact tests used and * Indicates significant difference in outcomes between patients with UG vs CG (p≤0.05).

Figure 2: Physician visits, hospital visits, and tests/assessments in the prior year for patients with UG vs. patients with CG



Mean (standard deviation) values displayed on charts.
CG-controlled gout; UG-uncontrolled gout.
*Indicated significant difference in outcomes between patients with UG vs CG (p≤0.05). Comparative analyses used t-tests (continuous variables) and Fisher's exact tests (categorical variables), with alpha<0.05.

Table 2: Clinical tests and assessments in the prior year for patients with UG vs. patients with CG

	Patients with UG	Patients with CG	p-value
Number of tests per patient who had the test to diagnose or monitor gout, mean (SD)			
SU tests	n=393 2.3 (1.6)	n=450 2.4 (2.0)	**<0.0001**
C-reactive protein	n=167 2.0 (1.6)	n=190 1.6 (1.6)	**0.0109**
Erythrocyte sedimentation rate	n=185 2.3 (1.8)	n=208 1.4 (1.6)	**<0.0001**
Renal function tests	n=134 3.0 (1.4)	n=182 2.4 (1.6)	**0.0004**
Complete blood tests	n=191 2.4 (1.5)	n=235 1.9 (1.5)	**0.0003**
Anti-CCP tests	n=106 1.3 (1.1)	n=120 0.8 (0.8)	**<0.0001**
Rheumatoid factor tests	n=119 1.2 (1.0)	n=134 0.8 (0.8)	**0.0001**
Antinuclear antibody tests	n=99 1.4 (1.0)	n=102 0.9 (0.9)	**0.0001**
Imaging	n=128 1.7 (1.3)	n=116 1.0 (0.9)	**<0.0001**
Synovial fluid (aspiration)	n=107 1.2 (1.3)	n=104 0.8 (0.9)	**0.0039**
Biopsy (of tophi/inflamed site)	n=20 1.8 (1.3)	n=13 0.9 (0.3)	**0.0255**
Blood pressure tests	n=143 3.4 (1.6)	n=188 2.7 (1.4)	**<0.0001**
Physician examinations	n=350 3.3 (1.4)	n=396 2.6 (1.4)	**<0.0001**
Tender joint counts	n=238 3.1 (1.5)	n=246 2.4 (1.3)	**<0.0001**
Swollen joint counts	n=226 3.0 (1.4)	n=231 2.3 (1.2)	**<0.0001**
Tophi counts	n=181 3.0 (1.4)	n=105 2.2 (1.2)	**<0.0001**
Tophi size measurements	n=72 3.0 (1.5)	n=38 2.1 (1.4)	**0.0018**

Anti-CCP; cyclic citrullinated peptide antibody, CG; controlled gout, UG; uncontrolled gout, SD: standard deviation, SU: serum urate. Sample sizes varied for each test/assessment as responses were provided for patients where physicians indicated that the test/assessment had been used in monitoring or diagnosis. Bold p-values showing a significant difference between patients with UG vs CG (p≤0.05).

Demographics and clinical characteristics at most recent visit

- A total of 102 physicians (46 rheumatologists, 22 nephrologists and 34 PCPs) completed surveys for 854 patients with gout; 400 had UG and 454 had CG.
- Compared to CG, a higher proportion of patients with UG **(Table 1)**:
  - Were Black or African American/African or Caribbean
  - Had renal disease and a higher mean Charlson Comorbidity Index
  - Required additional care, beyond what would usually be expected for a person of their age
- At the most recent visit, all patients were receiving ULT; allopurinol was the most common (63% UG; 70% CG), followed by febuxostat (29% UG; 23% CG).
- Overall clinical burden was significantly greater among patients with UG compared to those with CG, including higher SU, number of tophi and flares in the prior 12 months, and other symptoms such as tender/swollen joints **(Table 1)**.

CCRU and patient management

- Gout-related CCRU in the prior year was significantly higher among patients with UG than those with CG, including more physician visits, specialist involvement, and hospital visits (all p ≤ 0.05; **Figures 1 and 2a, and b**).
- Among patients with ≥1 hospital visit in the prior year, there was no significant difference between patients with UG (n=42) and CG (n=13) in the mean [SD] number of urgent care visits (0.6 [0.9] vs. 0.2 [0.4]; p=0.1769), emergency room visits (0.7 [1.4] vs 0.5 [0.5]; p=0.5696) and overnight admissions (0.5 [0.7] vs. 0.5 [0.9]; p=0.8007).
- Among patients who received gout-related clinical tests, those with UG had a significantly higher number performed in the prior year than those with CG **(Figure 2c),** with all types performed at a significantly higher rate in UG patients compared to those with CG **(Table 2)**.

LIMITATIONS

- Patients from the Adelphi Gout DSP™ do not constitute a true random sample; patients who consult more frequently are more likely to be included, therefore these findings may not be generalizable beyond the study population.
- Reporting of CCRU is based on information available to the physician in the patient's medical record at the time of the survey and therefore may not cover all resources used.

Acknowledgements

Data collection was undertaken by Adelphi Real World as part of an independent survey, entitled the Gout Disease Specific Programme™ (DSP). The DSP is a wholly owned Adelphi product, of which Sobi is one of multiple subscribers. Sobi did not influence the original survey through either contribution to the design of questionnaires or data collection. This poster was created by the authors in accordance with Good Publication Practice (GPP) 2022 guidelines (https://www.ismpp.org/gpp-2022). Sobi reviewed and provided feedback on the poster. The authors had full editorial control of the poster and provided their final approval of all content.

Disclosures

JS: No Disclosure. MB, JH, NM: Employee of Sobi, Inc. EG, ME, AH: Employee for Adelphi Real World and consultant for Sobi for this analysis. JAA: Advisor or review panel member and speaker/honoraria for Amgen.

References

1) Fitzgerald et al., Arth Car & Res.2020;72(6):744-60, 2) Anderson P. et al., Curr Med Res Opin. 2008;24(11):3063-72, 3) Babineaux SM. et al., BMJ Open. 2016;6(8):e010352, 4) Anderson P. et al., Curr Med Res Opin. 2023;39(12):1707-1, 5) Higgins V. et al., Metabolic Syndrome and Obesity: Targets and Therapy. 2016;9:371-80