Association Between Clinical Manifestations of Gout and Patient Reported Outcome Measures: Results of a Real-World Survey in The United States

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CONCLUSIONS

- **These findings demonstrate that worsening clinical indicators—including higher serum urate (SU) levels, more frequent flares, and the presence of tophi—are consistently associated with poorer quality of life (QoL) and greater activity impairment.**
- **Furthermore, this highlights the importance of comprehensive gout management strategies that address not only SU control but also the prevention and treatment of flares and tophi, in order to more effectively improve patient quality of life.**

INTRODUCTION AND OBJECTIVES

- Gout is the most common inflammatory arthritis in adults worldwide. It is caused by the deposition of monosodium urate crystals in joints and tissues, manifesting as painful, acute flares and the potential development of tophi.
- Studies suggest gout impacts patients' QoL, limiting patients' ability to perform self care and social activities.[1]
- There is limited evidence showing a relationship between gout clinical indicators such as SU, number of tophi and flares, and patient reported outcomes (PROs).
- This real-world evidence study of patients diagnosed with gout evaluates the association between PROs and gout clinical indicators.

METHODS

- Data were extracted from the Adelphi Real World Gout Disease Specific Programme™ (DSP), a cross-sectional survey of physicians (rheumatologists and primary-care physicians (PCPs)) and their patients with gout in the United States (US) between August 2023 - August 2024.
- The DSP has been previously described[2,3], validated[4], and demonstrated to be representative and consistent over time.[5]
- Patients were 18 or older and had a confirmed diagnosis of gout.
- Participating rheumatologists and PCPs managed ≥8 gout patients monthly.
- Physicians provided data for a consecutive series of patients, who met the inclusion criteria, to reduce selection bias.
- Physicians reported patients' SU and tophi at the most recent visit, and the number of flares in the 12 months prior to most recent visit.
- Patients completed multiple PRO tools
  - EQ-5D-5L (US): −0.573–1.0 (1 = full health; 0 = death; <0 = worse than death)
  - EQ-VAS: 0–100 (0 = worst, 100 = best imaginable health)
  - HAQ-DI: 0–3 (0 = no disability; 3 = severe disability)
  - WPAI: 0–100% (0% = no impairment; 100% = complete impairment)
- Descriptive analyses were used to assess physician reported patient demographics, treatments patterns and PROs at the time of most recent visit. Separate linear regression models examined the association of SU, tophi and flares in the prior 12 months with PROs, controlling for patient age and disease duration.

RESULTS

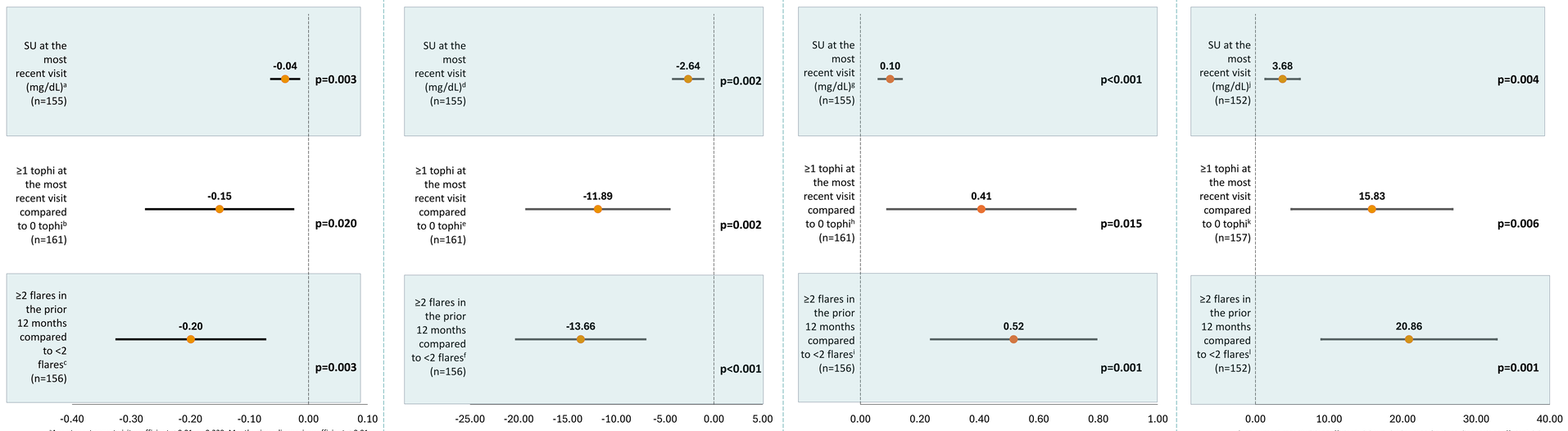
Demographics and clinical characteristics at the most recent visit

- Of 162 patients, 77 were managed by a rheumatologist, and 85 were managed by a PCP.
- The mean (standard deviation (SD)) patient age was 56.7 (16.2) years old, 73% were male, and mean (SD) disease duration was 6.6 (7.3) years.
- Patients had a mean (SD) SU of 6.4 (2.1) mg/dL, 19% had ≥1 tophi and 26% had ≥2 flares in the prior 12 months **(Table 1)**.

Treatment at the most recent visit

- At the most recent visit, 98% of patients were receiving urate-lowering therapy (ULT), with the most common being allopurinol (72%) followed by febuxostat (21%).
- Additionally, 31% and 24% of patients also were receiving NSAIDs and colchicine, respectively.

Figure 1: Forest plots showing the association between clinical manifestations of gout and PRO scores



[a]Age at most recent visit coefficient <-0.01; p=0.239. Months since diagnosis coefficient <-0.01; p=0.071

[b]Age at most recent visit coefficient <-0.01; p=0.079. Months since diagnosis coefficient <-0.01; p=0.419

[c]Age at most recent visit coefficient <-0.01; p=0.076. Months since diagnosis coefficient <-0.01; p=0.514

[d]Age at most recent visit coefficient -0.14; p=0.169. Months since diagnosis coefficient -0.01; p=0.518

[e]Age at most recent visit coefficient -0.17; **p=0.036**. Months since diagnosis coefficient 0.01; p=0.548

[f]Age at most recent visit coefficient -0.15; p=0.091. Months since diagnosis coefficient <0.01; p=0.767

[g]Age at most recent visit coefficient 0.01; **p=0.032**. Months since diagnosis coefficient <0.01; p=0.135

[h]Age at most recent visit coefficient 0.01; **p=0.002**. Months since diagnosis coefficient <0.01; p=0.676

[i]Age at most recent visit coefficient 0.01; **p=0.003**. Months since diagnosis coefficient <0.01; p=0.689

[j]Age at most recent visit coefficient -0.24; p=0.134. Months since diagnosis coefficient 0.04; p=0.188

[k]Age at most recent visit coefficient -0.19; p=0.207. Months since diagnosis coefficient 0.01; p=0.820

[l]Age at most recent visit coefficient -0.14; p=0.362. Months since diagnosis coefficient <-0.01; p=0.905

Abbreviations: HAQ-DI - Health Assessment Questionnaire -Disability Index, SU – serum urate, VAS – visual analogue score, WPAI – Work productivity and Activity Impairment
Patient age at most recent visit and months since diagnosis were controlled for in each model. Significant p values (p<0.05) are shown in bold. Error bars indicate 95% confidence intervals.

Table 1: Demographics and clinical characteristics at most recent visit

		Patients with gout (n=162)
Patient Demographics		
Age, mean (SD), years		56.7 (16.2)
Sex, n (%)		
	Male	118 (73)
	Female	44 (27)
Race, n (%)		
	White	108 (67)
	Black or African American/African or Caribbean	29 (18)
	East or Southeast Asian	13 (8)
	Other*	14 (9)
Time since diagnosis, Mean (SD), years		6.6 (7.3)
Patient Clinical Characteristics		
SU, mean (SD), mg/dL		n=155 6.4 (2.1)
Number of tophi, n (%)		n=161
	Tophi =0	131 (81)
	Tophi ≥1	30 (19)
Number of flares in prior year, n (%)		n=156
	Flares <2	116 (74)
	Flares ≥2	40 (26)

Abbreviations: mg/dL – milligrams per decilitre; SD - standard deviation; SU - serum urate
*Other ethnicities included Middle Eastern or North African, South or Central American Native, South Asian, Native Hawaiian or Pacific Islander and Other.
'Don't know' responses removed therefore samples vary per datapoint.

PRO scores at most recent visit

- PRO scores at the most recent visit are listed in **Table 2**.
- While the mean EQ-VAS score was consistent with general population reference values (80.5),[6] nominal differences were observed relative to general population values for the EQ-5D-5L (0.851) and HAQ-DI (0.25).[6,7]

Table 2: PRO scores at most recent visit

	Patients with gout
PRO score, Mean (SD)	
EQ-5D-5L	n=161 0.78 (0.27)
EQ-VAS	n=161 78.27 (16.73)
HAQ-DI	n=161 0.50 (0.65)
WPAI Activity Impairment	n=157 23.89 (25.26)

Abbreviations: HAQ-DI - Health Assessment Questionnaire - Disability Index, PRO – Patient reported outcomes, SD - standard deviation, VAS – visual analogue score, WPAI – Work productivity and Activity Impairment
Due to patient reported data being pen and paper, some patients chose not to answer all questions and therefore samples vary per PRO tool.

Association between clinical manifestations of gout and PRO scores

- Each 1-mg/dL increase in SU level was associated with progressively worse PROs, reflected by **(Figure 1)**.
  - Decreased EQ-5D-5L (−0.04) and EQ-VAS (−2.64),
  - Increased disability as measured by HAQ-DI (+0.10)
  - Greater activity impairment on the WPAI (+3.68%)
- Patients with one or more tophi experienced significantly diminished QoL relative to those without tophi **(Figure 1)**.
  - Decreased EQ-5D-5L (−0.15) and EQ-VAS (−11.89)
  - Increased disability as measured by HAQ-DI (+0.41)
  - Greater activity impairment on the WPAI (+15.83%)
- Compared with patients reporting <2 flares in the prior year, those with ≥2 flares had substantially worse PROs including **(Figure 1)**.
  - Decreased EQ-5D-5L (−0.20) and EQ-VAS scores (−13.66)
  - Increased disability as measured by HAQ-DI (+0.52)
  - Greater activity impairment on the WPAI (+20.86%)

LIMITATIONS

- Patients from the Adelphi Gout DSP™ do not constitute a true random sample, because patients who consult more frequently are more likely to be included in the sample, therefore these findings may not be generalizable beyond the study population.
- Due to the pen-and-paper nature of the patient reported data, some patients chose not to answer all parts of the survey. This resulted in different sample sizes across the analyses.
- Demographics such as body mass index and comorbidities were missing for many patients so were not included as covariates in the regression analysis.
- Data was collected at a single timepoint, rather than longitudinally.

Disclosures

AS: Speaker/Honoraria: Abbvie, Amgen, GSK, Astrazeneca, UCB, AM
MB and JH are employees of Sobi Inc
ME, EG and AH are employees of Adelphi Real World and acted as consultants to Sobi for this analysis
TM has received previous research support from Horizon Therapeutics (Amgen); has served as a consultant for Horizon, Merck, UCB, and Olatec Therapeutics; and receives royalties from Elsevier and UpToDate.

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