The Impact of Elevated Serum Uric Acid Levels and Tophi on HRQOL and Daily Functioning in Patients with Uncontrolled Gout

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CONCLUSIONS

- Patients with uncontrolled gout (UG) experience significant challenges and reduced health-related quality of life (HRQOL) due to UG, despite being on active treatment with urate-lowering therapy (ULT).
- Impairments in HRQOL, work productivity, and ability to carry out daily activities are exacerbated by a history of tophi or the presence of elevated serum uric acid (sUA) levels.
- These findings underscore the need for personalized care and timely or escalated therapeutic approaches to more effectively manage the disease burden.

INTRODUCTION

- Uncontrolled gout (UG) is classified as elevated sUA levels and persistent symptoms despite treatment with ULT.[1,2]
- Manifestations of UG, such as tophi and flares, are associated with chronic pain and physical disability.[3]
- While the overall burden of UG is recognized, there is limited research assessing the impact of clinical symptoms on HRQOL and daily functioning.

OBJECTIVE

- This real-world study aimed to evaluate the impact of elevated sUA levels or tophi on HRQOL, activities of daily living (ADLs), and work productivity in patients with UG.

METHODS

Study Design

- A cross-sectional web-based survey was conducted among adult patients with a physician-confirmed diagnosis of UG in the United States (US).
- Inclusion criteria: ≥18 years of age; history of symptomatic gout (i.e., ≥2 gout flares within 12 months or presence of ≥1 gout tophus, or current diagnosis of symptomatic chronic gouty arthritis); currently taking oral ULT or treated with pegloticase in the past 18 months.
- Data collected included demographics, clinical characteristics, treatment information, and patient reported outcomes measured by ADLs, 12-item Short Form Survey version 2 (SF-12®v2), and Work Productivity and Activity Impairment (WPAI).
- Two separate subgroup analyses were conducted:
  - **History of tophi** (history vs. no history of tophi)
  - **sUA level from most recent test** (≥6mg/dL vs. <6mg/dL)

Statistical Analyses

- Data were analyzed descriptively.
- Unadjusted differences between subgroups were tested using Wilcoxon rank-sum tests for continuous variables and chi-square or Fisher's exact tests for categorical variables.

RESULTS

Tophi Subgroup

Patient Demographics

- Among 100 patients included in the tophi analysis, 35% had a self-reported history of tophi (Table 1).

Table 1. Patient Demographics by History of Tophi

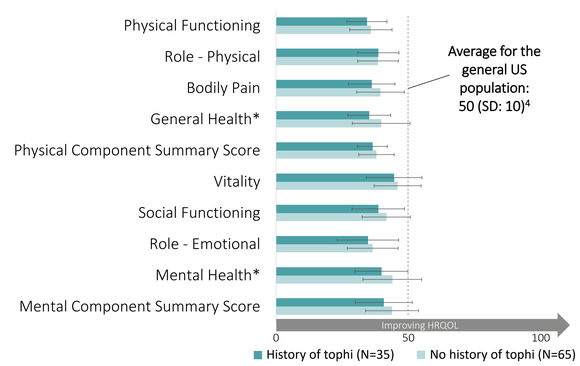
Characteristic	History of Tophi (N=35)	No History of Tophi (N=65)
Mean age, years (SD)	56.7 (13.8)	53.0 (12.8)
Male, n (%)	22 (62.9)	41 (63.1)
Ethnicity, n (%)		
White	15 (42.9)	32 (49.2)
Black/African American	8 (22.9)	18 (27.7)
Hispanic/Latino	6 (17.1)	8 (12.3)
Asian/Pacific Islander	3 (8.6)	2 (3.1)
Other	3 (8.6)	5 (7.7)
US region of residence, n (%)		
Northeast	24 (68.6)	35 (53.9)
South	4 (11.4)	18 (27.7)
West	5 (14.3)	8 (12.3)
Midwest	2 (5.7)	4 (6.2)
Insurance coverage*, n (%)		
Commercial	15 (42.9)	38 (58.5)
Medicare	14 (40.0)	17 (26.2)
Medicaid	9 (25.7)	8 (12.3)
VA/DOD/Tricare	0 (0.0)	3 (4.6)

Abbreviations: DOD=Department of Defense, n=number of participants, N=total number, VA=Veterans Affairs, SD=standard deviation, US=United States. *Patient may have more than one type of insurance coverage. Note: There were no statistically significant differences in baseline characteristics between patients with a history of tophi and patients with no history of tophi.

Quality of Life

- Patients with a history of tophi reported lower general health (mean 35.2 vs. 39.7; p=.044) and mental health (39.8 vs. 43.9; p=.050) scores than those without tophi (Figure 1).
- Mean HRQOL scores for both subgroups were descriptively lower across all domains compared to the published general US population norms.

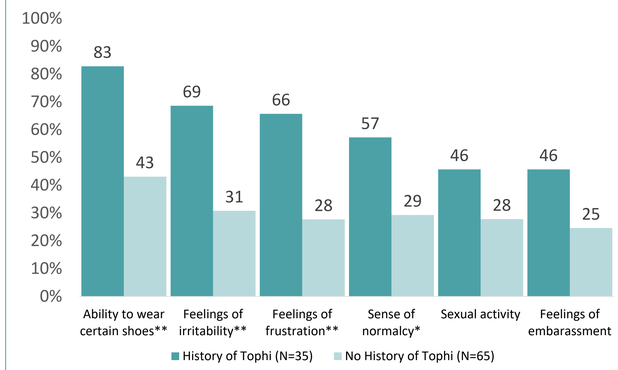
Figure 1. Mean Patient SF-12v2 Scores by History of Tophi



Abbreviations: HRQOL=health-related quality of life, N=total number, SD=standard deviation, SF-12v2= 12-item Short Form Survey version 2, US=United States. Note: SF12v2 is a validated measure that assesses physical and mental HRQOL (0-100; higher values indicting better HRQOL). Error bars represent SD for SF-12 values. *p<0.05, **p<0.01, ***p<0.001

- Patients with a history of tophi reported greater emotional burden, with significantly more indicating that UG impacts feelings of irritability (68.6% vs. 30.8%; p=.002), frustration (65.7% vs. 27.7%; p=.004), and sense of normalcy (57.2% vs. 29.3%; p=.039) (Figure 2).
- Impact on ability to wear certain shoes was also significantly higher for those with a history of tophi (82.8% vs. 43.1%; p=.002).

Figure 2. Impact of UG on Patient HRQOL by History of Tophi§



Abbreviations: HRQOL=health-related quality of life, UG=uncontrolled gout, N=total number. § Percent of participants responding that they are affected 'quite a bit' or 'very much.' Note: ADL burden was rated on a five-point Likert scale (i.e., not at all, a little bit, somewhat, quite a bit, very much). *p<0.05, **p<0.01, ***p<0.001

Work Productivity and Activity Impairment

- Patients with and without history of tophi experienced substantial overall work impairment (52.5% vs. 52.5%; p>.999) and overall activity impairment (61.7% vs. 58.9%; p=.445) (Table 2).

Table 2. Patient WPAI Scores by History of Tophi

	History of Tophi (N=35)	No History of Tophi (N=65)	p-value
Overall activity impairment, mean (SD)	61.7 (28.3)	58.9 (24.4)	.445
Employed, n (%)	18 (51.4)	41 (63.1)	.259
Hours worked in past 7 days, mean (SD)*	29.9 (12.1)	33.2 (10.3)	.250
Missed work hours in the 7 days prior to the survey due to UG, mean (SD)*	6.8 (7.4)	6.8 (10.8)	.423
WPAI percentage scores, mean (SD)			
Absenteeism*	18.0 (19.1)	13.8 (19.9)	.350
Presenteeism*	45.9 (28.1)	49.0 (31.7)	.733
Overall work impairment*	52.5 (30.2)	52.5 (32.5)	>.999

Abbreviations: n=number of participants, N=total number, SD=standard deviation, UG=uncontrolled gout, WPAI=Work Productivity and Activity Impairment. Note: WPAI is a validated measure that reflects work and activity impairment (0-100%; higher values indicating greater impact). *Among those employed (history of tophi: n=17, no history of tophi: n=40)

sUA Level Subgroup

Patient Demographics

- The sUA analysis included 94 patients for whom recent sUA test results were available; 76.6% had sUA levels ≥6mg/dL (Table 3).

Table 3. Patient Demographics by sUA Level

Characteristic	sUA ≥6mg/dL (N=72)	sUA <6mg/dL (N=22)
Mean age, years (SD)	53.4 (14.0)	59.6 (9.0)
Male, n (%)	48 (66.7)	12 (54.6)
Ethnicity, n (%)		
White	34 (47.2)	12 (54.6)
Black/African American	21 (29.2)	3 (13.6)
Hispanic/Latino	8 (11.1)	4 (18.2)
Asian/Pacific Islander	3 (4.2)	2 (9.1)
Other	6 (8.3)	1 (4.6)
US region of residence, n (%)		
Northeast	40 (55.6)	15 (68.2)
South	14 (19.4)	6 (27.3)
West	13 (18.1)	0 (0.0)
Midwest	5 (6.9)	1 (4.6)
Insurance coverage*, n (%)		
Commercial	39 (54.2)	9 (40.9)
Medicare	21 (29.2)	10 (45.5)
Medicaid	14 (19.4)	2 (9.1)
VA/DOD/Tricare	1 (1.4)	2 (9.1)

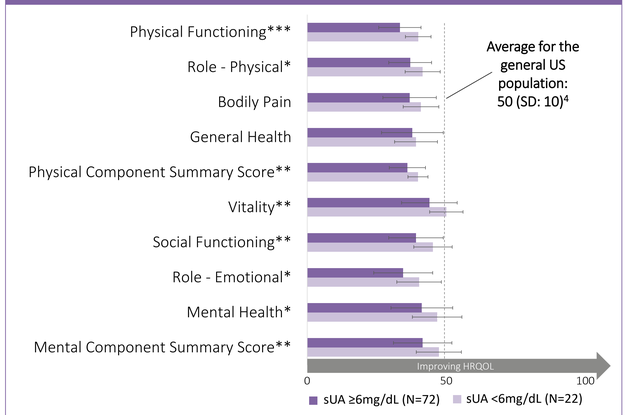
Abbreviations: DOD=Department of Defense, n=number of participants, N=total number, sUA=serum uric acid, VA=Veterans Affairs, SD=standard deviation, US=United States. *Patient may have more than one type of insurance coverage. Note: There were no statistically significant differences in baseline characteristics between patients with sUA ≥6mg/dL and patients with sUA <6mg/dL.

Treatment Experience and Symptoms

- Patients with sUA ≥6mg/dL experienced significantly more gout flares compared to those with sUA <6mg/dL (83.3% vs. 59.1%; p=.017).
- The mean number of flares in the last six months was 3.9 for patients with sUA ≥6mg/dL vs. 3.3 for those with sUA <6mg/dL.

Quality of Life

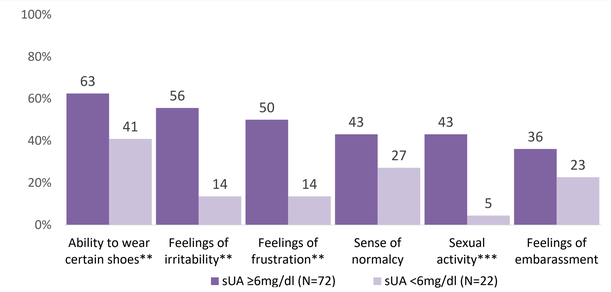
Figure 3. Mean Patient SF-12v2 Scores by sUA Level



Abbreviations: HRQOL=health-related quality of life, N=total number, SD=standard deviation, SF-12v2= 12-item Short Form Survey version 2, sUA=serum uric acid, US=United States. Note: SF12v2 is a validated measure that assesses physical and mental HRQOL (0-100; higher values indicting better HRQOL). Error bars represent SD for SF-12 values. *p<0.05, **p<0.01, ***p<0.001

- Patients with sUA ≥6mg/dL reported lower physical (36.0 vs. 39.8; p=.008) and mental (41.5 vs. 47.3; p=.009) summary component scores (Figure 3).
- The largest differences in mean scores were in physical functioning (33.3 vs. 39.9; p<.001), vitality (43.9 vs. 50.0; p=.002), and social functioning (39.1 vs. 45.2; p=.007).

Figure 4. Impact of UG on Patient HRQOL by sUA Level§



Abbreviations: HRQOL=health-related quality of life, UG=uncontrolled gout, N=total number, sUA=serum uric acid. § Percent of participants responding that they are affected 'quite a bit' or 'very much.' Note: ADL burden was rated on a five-point Likert scale (i.e., not at all, a little bit, somewhat, quite a bit, very much). *p<0.05, **p<0.01, ***p<0.001

- Patients with sUA ≥6mg/dL experienced a greater emotional burden, with significantly more patients reporting that UG impacts their feelings of frustration (50.0% vs. 13.6%; p=.013) and irritability (55.6% vs. 13.6%; p=.002 (Figure 4).
- The impact on sexual activity (43.1% vs. 4.5%; p=.001) and ability to wear certain shoes (62.5% vs. 40.9%; p=.010) were also significantly higher for patients with sUA ≥6mg/dL.

Work Productivity and Activity Impairment

- Patients with sUA ≥6mg/dL reported greater overall activity impairment compared to those with sUA <6mg/dL (64.3% vs. 51.4%; p=.017) (Table 4).

Table 4. Patient WPAI Scores by sUA Level

	sUA ≥6mg/dL (N=72)	sUA <6mg/dL (N=22)	p-value
Overall activity impairment, mean (SD)	64.3 (26.0)	51.4 (19.8)	**.017**
Employed, n (%)	43 (59.7)	11 (50.0)	.420
Hours worked in past 7 days, mean (SD)*	36.4 (3.7)	31.0 (12.0)	.226
Missed work hours in the 7 days prior to the survey due to UG, mean (SD)*	8.3 (10.7)	1.5 (2.3)	.137
WPAI percentage scores, mean (SD)			
Absenteeism*	18.3 (20.9)	4.0 (5.4)	.163
Presenteeism*	53.7 (32.1)	38.2 (19.4)	.129
Overall work impairment*	58.3 (32.8)	40.8 (19.0)	.073

Abbreviations: n=number of participants, N=total number, SD=standard deviation, sUA=serum uric acid, UG=uncontrolled gout, WPAI=Work Productivity and Activity Impairment. Note: WPAI is a validated measure that reflects work and activity impairment (0-100%; higher values indicating greater impact). *Among those employed (sUA ≥6mg/dL: n=41, sUA <6mg/dL: n=11)

Study Limitations

- Observational, retrospective data collection relies on self-reported information which could be influenced by social desirability bias.
- Due to the limited sample size, results may not be generalizable to the broader UG population.

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DISCLOSURES

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