

Time Trends and Predictors of Gout Remission Over 6 Years

Adwoa Dansoa Tabi-Amponsah,¹ Sarah Stewart,² Greg Gamble,¹ Lisa K. Stamp,³ William J. Taylor,⁴ and Nicola Dalbeth¹

Objective. This study aims to describe the trends in remission rates over 6 years of follow-up among people with gout taking urate-lowering therapy (ULT) and to identify variables that predict remission.

Methods. A post hoc analysis was conducted using data from the Cardiovascular Safety of Febuxostat or Allopurinol in Patients with Gout (CARES) trial, which enrolled people with gout and cardiovascular disease randomized to febuxostat or allopurinol. Gout remission over 6 years of follow-up was measured in participants with at least 1 year of follow-up data using the simplified gout remission definition, requiring the fulfillment of three domains: (1) no gout flares during the past year, (2) at least two serum urate measurements <0.36 mmol/L during the past year, and (3) no tophus. Logistic regression was used to identify baseline predictors of remission.

Results. Achievement of remission increased from 37.4% of participants (1,593/4,259) at year 1 to 63.1% (322/510) at year 6. Over the 6 years, 59.4% of participants achieved remission at least once. More participants receiving febuxostat achieved remission during the first 2 years, primarily because of a higher number achieving the serum urate remission domain. In multivariable analysis, baseline age, race, greater disease severity, presence of comorbidities, and febuxostat treatment were variables significantly associated with remission.

Conclusion. On ULT, fulfillment of remission increases over time and remission can be achieved in most patients. Baseline predictors, including demographics, comorbidities, and disease severity, may be useful to identify people with gout who need more proactive management to achieve remission.

INTRODUCTION

Gout is a chronic rheumatic disease of monosodium urate crystal deposition in the joints, tendons, and other tissues, resulting from sustained elevation of serum urate levels. Gout is characterized by recurrent episodes of acute inflammatory arthritis, known as gout flares.¹ If untreated, gout may progress to the development of subcutaneous tophi and chronic synovitis with joint damage.¹

For chronic rheumatic diseases, remission is defined as “either a complete absence of disease activity or a level of disease activity so low that it is not troublesome to the patient and portends a later good prognosis.”² In current gout management and research, the primary strategy is “treat to serum urate-target of <0.36 mmol/L” using urate-lowering therapy (ULT).³ In 2016, a composite measure of disease activity, “remission,” was introduced by rheumatologists and gout researchers with the

development of preliminary gout remission criteria, which includes the following: no gout flares and serum urate level of <0.36 mmol/L (6 mg/dL), with no values ≥0.36 mmol/L (6 mg/dL) and absence of tophi; pain caused by gout <2 on a 10-point scale, with no values ≥2; and patient global assessment of gout disease activity <2 on a 10-point scale, with no values ≥2.⁴ The 2016 preliminary criteria required that the serum urate, pain, and patient global assessment domains must be measured at least twice over 12 months.⁴ Subsequently, a simplified gout remission criteria without patient-reported outcomes has been developed and compared with the 2016 preliminary criteria and has shown good face validity, concurrent validity, responsiveness, and discrimination.^{5–7}

To date, analyses of gout remission have been conducted on studies that were 1 to 2 years in length.^{5–7} However, the longitudinal trends in gout remission status over more extended periods are unknown. Furthermore, baseline variables that influence

¹Adwoa Dansoa Tabi-Amponsah, BBiomedSc (Hons), Greg Gamble, MSc, Nicola Dalbeth, MBChB, MD, FRACP: University of Auckland, Auckland, New Zealand; ²Sarah Stewart, PhD: University of Auckland and Auckland University of Technology, Auckland, New Zealand; ³Lisa K. Stamp, MBChB, PhD, FRACP: University of Otago, Christchurch, Christchurch, New Zealand; ⁴William J. Taylor, MBChB, PhD, FRACP: University of Otago, Wellington, Wellington, New Zealand.

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Address correspondence via email to Nicola Dalbeth, MBChB, MD, FRACP, at n.dalbeth@auckland.ac.nz.

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SIGNIFICANCE & INNOVATIONS

- Gout remission was analyzed using the simplified gout remission criteria, a definition for clinical remission in gout recently endorsed by the Gout, Hyperuricemia, and Crystal-Associated Disease Network.
- The fulfillment of gout remission over extended periods is currently underexplored in the literature. This is the first study to evaluate gout remission over a 6-year clinical trial, focusing on trends in rates of remission over time and identifying baseline variables associated with achieving remission.
- In this study, there was an increase in the rates of remission over time and baseline age, race, greater disease severity, presence of comorbidities, and febuxostat treatment were variables significantly associated with remission.

fulfillment of gout remission over more extended periods are unknown. Using this new simplified definition of gout remission, this post hoc analysis of the Cardiovascular Safety of Febuxostat or Allopurinol in Patients With Gout and Cardiovascular Comorbidities⁸ (CARES) trial⁸ aimed to describe the time trends in remission rates over 6 years of follow-up among people with gout receiving ULT and to identify baseline variables that predict remission.

PATIENTS AND METHODS

A post hoc analysis was conducted using data from the CARES trial.⁸ The CARES trial dataset was accessed through the Vivli Platform (request number 8874). This trial has previously been described⁸; in brief, all participants had gout according to the 1977 American Rheumatism Association preliminary gout classification criteria⁹ and a history of major cardiovascular disease. Participants were assigned 1:1 to receive once-daily febuxostat or allopurinol, which were titrated to achieve serum urate concentration <0.36 mmol/L (6 mg/dL). Participants were observed prospectively from baseline through to dropout, death, or the end of the 6-year study, whichever occurred first.⁸

Gout remission definition and timepoints. In this analysis, gout remission was assessed using the simplified definition: (a) absence of gout flares over 12 months (gout flares domain), (b) serum urate <0.36 mmol/L at least twice over 12 months at equal distances apart (serum urate domain), and (c) absence of tophus (tophus domain). Study visits were scheduled every 6 months. Remission at year 1 was measured using clinical assessments at month 6 and month 12, year 2 was measured using clinical assessments at month 18 and month 24, year 3 was measured at month 30 and month 36, year 4 at month

42 and month 48, year 5 at month 54 and month 60, and year 6 at month 66 and month 72. Remission was determined for participants with serum urate, tophi, and gout flare assessments from these visits (Supplementary Figure 1).

Statistical analysis. In the CARES trial, there were 6,190 participants enrolled at baseline who received trial medication. There was significant loss to follow-up (45% of participants missed at least one study visit), and 56.6% discontinued the study drug. In this analysis, only participants with at least 1 year of follow-up data were included, and those who discontinued the study drug over the study period were still included in the analysis. Missing data were handled using available case analysis, in which remission was determined only for participants with available data at the analyzed time points without imputation.

Baseline demographics and clinical variables were summarized using standard descriptive statistics, including mean, SD, count, and percent, as appropriate. Remission status and fulfillment of the individual remission domains were described using count and percent.

Logistic regression was used to evaluate the association between intervention group and the fulfillment of individual domains within the simplified criteria, as well as to assess the association between intervention group and remission status, for each year. To account for clustering of patients within years, a generalized linear mixed model with nested random effects was applied to estimate intervention effects on overall remission status. Random intercepts were included for patients and for years nested within patients, with a compound symmetry covariance structure assumed for the repeated measurements.

The ‘survival’ package in R was used to estimate the median time to first remission for both interventions. Right censoring was applied accordingly, accounting for participants who were lost to follow-up or did not reach remission over the 6-year period. Loss to follow-up was treated similarly to not reaching remission because it was approximately uniform across treatment groups and did not differ systematically. As such, it was assumed to be a random event rather than a competing risk for the event (remission). Cox regression was used to examine the association between the intervention groups and time to remission. The proportional hazards assumption was assessed using Schoenfeld residuals, which indicated that the proportional hazards assumption was met.

Baseline factors associated with the fulfillment of remission at least once over 6 years (selected based on expert clinical knowledge) were assessed using univariable and multivariable logistic regression analysis. The number of variables to be used in the final multivariable model was reduced by selecting from candidate baseline variables with associations of $P < 0.15$ in univariable analyses. From these candidate variables, backward elimination and a modern selection strategy, lasso logistic regression, were used to identify predictor(s) for achieving gout remission.^{10–12}

Lasso regression includes an L1 penalty, which encourages sparsity by shrinking some coefficients to exactly zero. This makes lasso particularly useful for variable selection, as it automatically removes irrelevant or less important variables from the model.¹⁰ From these approaches, a final multivariable logistic regression model was produced incorporating variables chosen based on biologic plausibility, parsimony, and goodness of fit. Statistical analysis was performed using R software version 4.3.1 and GraphPad Prism software version 9.3.1.; $P < 0.05$ was used to denote statistical significance.

RESULTS

Baseline clinical characteristics. The baseline clinical characteristics of those used in this analysis and the overall number of participants randomized are reported in Supplementary Table 1. Clinical characteristics were similar across both groups. Among the 4,301 included in the analysis, 2,158 were randomized to receive allopurinol and 2,143 to receive febuxostat. Overall, 21% of the participants had tophi at baseline, 61% had a serum urate concentration <0.54 mmol/L, and 11% had not experienced a gout flare in the past year or more. Of the participants analyzed, 1,693/4,301 discontinued the study drug and this was similar between the intervention groups: 832 (39%) in the allopurinol group and 861 (40%) in the febuxostat group.

Fulfillment of remission over 6 years. Achievement of remission increased over the 6 years. At year 1, 37.4% of participants (1,593/4,259) were in remission; at year 2, 47.8% (1,472/3,081); at year 3, 53.1% (1,182/2,225); at year 4, 55.3% (863/1,560); at year 5, 59.0% (589/999) and at year 6, 63.1% (322/510) (Figure 1).

Participants in the febuxostat group were significantly more likely to fulfill remission at year 1 and year 2. From year 3 through to year 6, there was no difference in the proportion of participants who achieved remission between the intervention groups (Table 1). Overall, when accounting for the clustering of patients within years, those in the febuxostat group had higher odds of getting in remission over the 6 years compared with those in the allopurinol group (odds ratio [OR] 1.29; 95% confidence interval [CI] 1.11–1.49; $P < 0.001$) (Table 1). Additionally, the proportion of missing data was comparable between the intervention groups over the 6 years, indicating that missingness was not systematically related to the intervention and did not bias the comparison of group performance (Supplementary Table 2).

Over the 6 years, 59.4% (2,554/4,301) of all enrolled participants with sufficient data achieved remission at least once. Among participants who achieved remission, 67% had remained on the study drug over the duration of the study.

The median time to the first episode of remission was 2 years for both intervention groups. Those in the febuxostat group had a

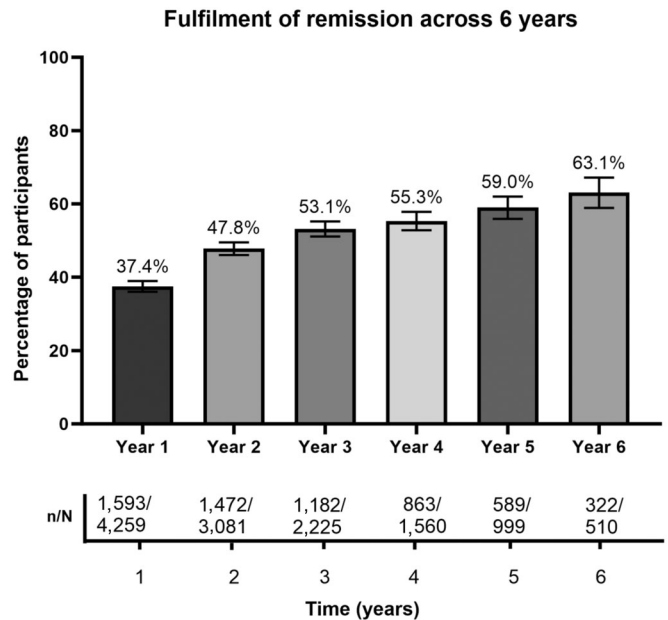


Figure 1. Fulfillment of the simplified remission criteria over 6 years.

10% higher hazard of achieving remission at any given time, with a hazard ratio of 1.10 (95% CI, 1.02–1.19; $P = 0.02$). (Figure 2).

Most participants in remission at year 1 maintained their remission status in subsequent years, ranging from 73.2% to 76.0% of participants (Figure 3). Among those who fulfilled remission at year 6, half (50.3%) had also fulfilled remission at year 1 (Figure 3).

Fulfillment of individual remission domains over 6 years. Fulfillment of the individual domains increased consistently over the 6 years. Data for individual domains are shown in Supplementary Figure 2.

Gout flares domain. At year 1, the gout flares domain was fulfilled by 71.2% of participants (3,033/4,259), rising to 85.8% at year 2 (2,645/3,081), 90.0% at year 3 (2,002/2,225) and year 4 (1,404/1,560), 92.3% at year 5 (922/999), and 92.7% in year 6 (473/510).

Serum urate domain. At year 1, the serum urate domain was fulfilled by 61.0% of participants (2,596/4,259), rising to 62.7% at year 2 (1,931/3,081), 65.2% at year 3 (1,450/2,225), 66.5% at year 4 (1,037/1,560), 67.8% at year 5 (677/999), and 69.8% at year 6 (356/510). In those not reaching the remission urate target over the 6 years, the mean \pm SD serum urate concentration was 0.43 ± 0.05 mmol/L.

Tophus domain. At year 1, the tophus domain was fulfilled by 85.2% at year 1 (3,629/4,259), rising to 86.4% at year 2 (2,663/3,081), 88.3% at year 3 (1,965/2,225), 90.4% at year 4 (1,411/1,560), 93.1% at year 5 (930/999), and 95.5% at year 6 (487/510).

Fulfillment of domains by intervention group. There was no difference in fulfillment of the gout flares domain between the

Table 1. Fulfillment of remission by intervention*

	Febuxostat group, n/N (%; 95% CI)	Allopurinol group, n/N (%; 95% CI)	OR (95% CI) ^a	P value
Year 1	828/2,118 (39.1; 37.0–41.2)	765/2,141 (35.7; 33.7–37.8)	1.15 (1.02–1.31)	0.02
Year 2	778/1,551 (50.2; 47.7–52.7)	694/1,530 (45.4; 42.9–47.9)	1.21 (1.05–1.40)	0.008
Year 3	612/1,125 (54.4; 51.5–57.3)	570/1,100 (51.8; 48.9–54.8)	1.11 (0.94–1.31)	0.22
Year 4	446/789 (56.5; 53.1–60.0)	417/771 (54.1; 50.6–57.6)	1.10 (0.90–1.35)	0.33
Year 5	310/503 (61.6; 57.3–65.8)	279/496 (56.3; 51.9–60.6)	1.25 (0.97–1.61)	0.08
Year 6	170/263 (64.6; 58.7–70.2)	152/247 (61.5; 55.3–67.4)	1.14 (0.80–1.64)	0.47
Overall ^b	–	–	1.29 (1.12–1.49)	0.006

* CI, confidence interval; OR, odds ratio.
^a Participants assigned to allopurinol were used as the reference.
^b Adjusted for the clustering of patients within years.

intervention groups. However, at years 1 and 2, participants in the febuxostat group were significantly more likely to fulfill the serum urate domain. Also, at year 6, participants in the febuxostat group were significantly more likely to fulfill the tophus domain (Supplementary Tables 3–5).

Baseline predictors of at least one episode of remission. In the univariable analyses, many baseline factors were significantly associated with remission (Supplementary Table 6). Race, disease severity, and the presence of certain comorbidities were particularly associated with lower odds of achieving remission. The multivariable model is shown in Table 2; 17.1% of the variance in remission status was explained by this model ($\chi^2 = 576.75$, $df = 20$, $P < 0.001$; Nagelkerke $R^2 = 0.171$; C-index = 0.709).

In the multivariable model, baseline age remained an independent predictor of remission. Older participants (aged ≥ 65 years) had significantly higher odds of achieving remission (OR 1.30; 95% CI 1.14–1.49) at least once over the 6 years. Race was also another demographic factor that remained an independent predictor. Compared with White participants, participants who were Black and from “other” races had significantly lower odds of achieving remission: the OR for Black participants was 0.65 (95% CI 0.54–0.78) and 0.59 (95% CI 0.48–0.72) for “other” participants.

Disease duration remained an independent predictor. Compared with participants with disease duration < 5 years, the OR for participants with disease duration 5 to 10 years was 0.80 (95% CI 0.66–0.97) and for those with disease duration > 10 years was 0.78 (95% CI 0.67–0.91). The presence of tophi, experience of multiple gout flares in the past year or more, and higher serum

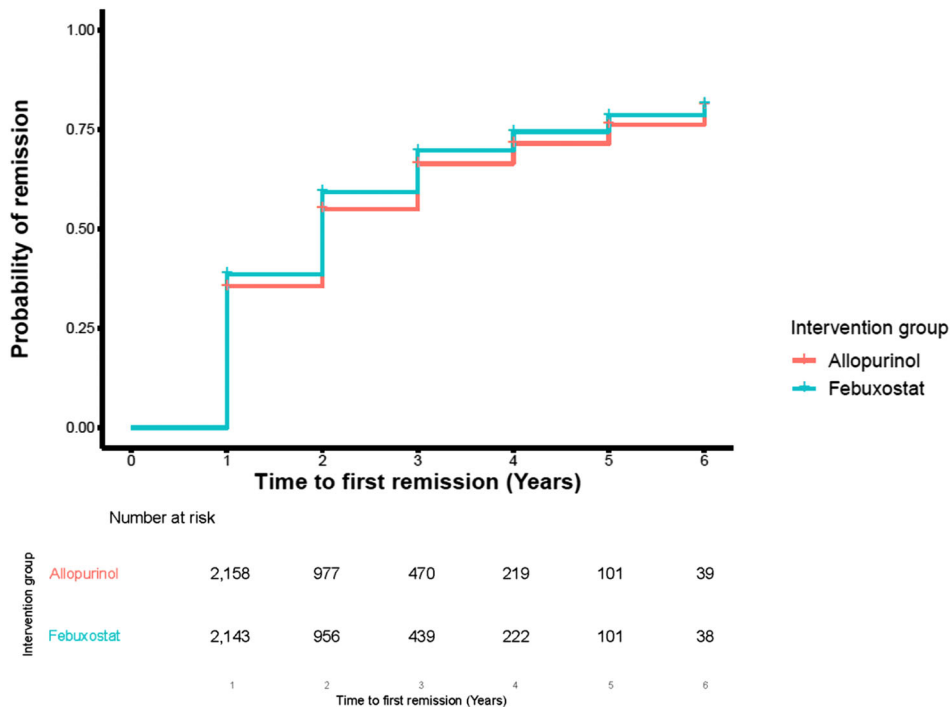


Figure 2. Survival curve for the time to the first episode of remission between the allopurinol and febuxostat intervention groups. Color figure can be viewed in the online issue, which is available at <http://onlinelibrary.wiley.com/doi/10.1002/acr.25584/abstract>.

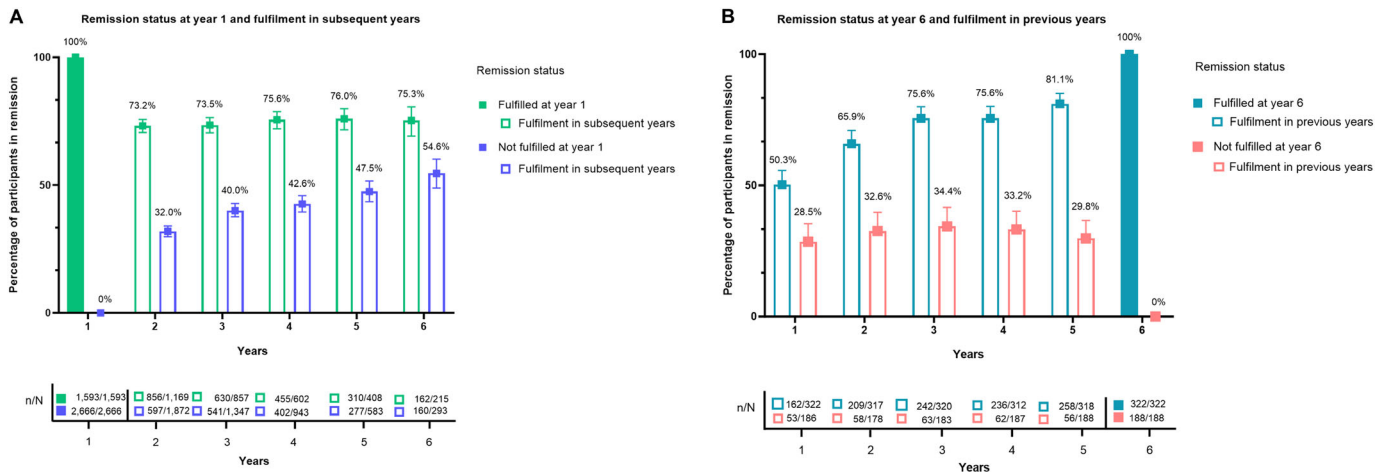


Figure 3. (A) Remission status at year 1 and fulfillment in subsequent years. (B) Remission status at year 6 and fulfillment in previous years.

urate concentrations all remained independent predictors negatively associated with experiencing at least one episode of remission. Neutrophil-lymphocyte ratio (NLR) was also an independent predictor; a higher NLR was associated with lower odds of experiencing remission, with an OR of 0.95 (95% CI 0.95–0.99).

The presence of comorbidities, including a history of diabetes, cerebrovascular disease, congestive heart failure, or peripheral vascular disease, were each independent predictors associated with lower odds of remission. With a history of diabetes, the OR for an episode of remission was 0.80 (95% CI 0.69–0.91); for cerebrovascular disease, the OR was 0.82 (95% CI 0.70–0.96); for congestive heart failure, it was 0.79 (95% CI 0.63–0.96); and for peripheral vascular disease, it was 0.78 (95% CI 0.63–0.96). In the multivariable model, febuxostat remained associated with greater odds of remission, with an OR of 1.23 (95% CI 1.08–1.40; $P = 0.002$).

DISCUSSION

A key goal of gout management should be the achievement of remission and then maintenance of remission in subsequent years. In this study, we described remission status over 6 years in people with gout and cardiovascular disease, using the simplified gout remission criteria. We also identified baseline factors that influence the fulfillment of gout remission over this period.

Our analysis has shown that gout remission is difficult to achieve in the first year of ULT. However, over time there was an increase in the rates of people achieving remission, from 37.4% at year 1 to 63.1% at year 6. This trend in the rates of remission over time is consistent with previous analyses. In our previous analysis of the simplified gout remission definition in a population of people with erosive gout receiving oral ULT over 2 years, rates of remission increased from 27% at year 1 to 44% at year 2.⁷ Similarly, in our analysis comparing nurse-led care with usual gout care, remission increased from 18% at year 1 to 43% at year 2.⁵

In an observational treat-to-target patient cohort with 5 years of follow-up, Uhlig et al¹³ reported that rates of remission increased from 7.7% at year 1 to 45.4% at year 2 and 58.6% at year 5.

Of the individual domains in this clinical trial, the serum urate domain appeared to be the most difficult to achieve as it had the lowest rates of fulfillment over time, with 69.8% of participants fulfilling it in year 6. This may be because of the maximum dose of ULT given to participants, which was 80 mg daily febuxostat and 600 mg daily allopurinol in participants with normal kidney function. Participants did not get further dose titration once these maximum doses were reached, as opposed to what may happen in clinical practice. This may also be because of the high rates of study drug discontinuation in this study. Low rates of continuous ULT are common in clinical practice and have been reported in previous studies, including a previous meta-analysis that calculated the overall pooled proportion of patients receiving regular uninterrupted ULT across studies from Europe, North America, Oceania, and Asia to be 26% (95% CI 18%–35%).¹⁴ This highlights a key issue in gout management and an area of focus for the achievement of gout remission.

In contrast, the gout flare domain and tophus domain had higher rates of fulfillment, with 92.7% of participants and 95.5% of participants, respectively, at year 6. This, however, can vary depending on the baseline disease severity, as we observed in our study, and as previously reported by Alvarado-de la Barrera et al¹⁵ in an observational study in which 44% of the participants had five or more tophi at baseline and were categorized as having severe gout. In that study, none were able to fulfill the tophus domain over the 5-year study period. The number and size of the tophi was the key reason for why some participants were unable to achieve gout remission, defined using the 2016 preliminary gout remission criteria. Collectively, these data show that once tophi are present, it takes a long time to achieve gout remission and highlights that in aiming for gout remission, people with gout need to begin treatment as early as possible (before tophus development) to increase the chances of being able to achieve remission.

Table 2. Reduced model for baseline variables associated with at least one episode of gout remission over 6 years*

Baseline variables	OR (95% CI)	P value
Age		
<65 y	Ref	–
≥65 y	1.30 (1.14–1.49)	<0.001
Sex		
Male	1.08 (0.89–1.31)	0.43
Female	Ref	–
Race		
Black	0.65 (0.54–0.78)	<0.001
White	Ref	–
Other	0.59 (0.48–0.72)	<0.001
Disease duration		
<5 y	Ref	–
5 to <10 y	0.80 (0.66–0.97)	0.02
≥10 y	0.78 (0.67–0.91)	0.002
Presence of tophus		
0	Ref	–
1 to <5	0.31 (0.26–0.36)	<0.001
≥5	0.10 (0.07–0.15)	<0.001
Serum urate		
<0.54 mmol/L	Ref	–
0.54–0.59 mmol/L	0.83 (0.70–0.98)	0.03
0.60–0.65 mmol/L	0.73 (0.59–0.91)	0.005
>0.65 mmol/L	0.60 (0.46–0.77)	<0.001
Number of gout flares in the last year		
0	Ref	–
1–3	0.64 (0.50–0.80)	<0.001
4–6	0.53 (0.41–0.70)	<0.001
>6	0.51 (0.38–0.68)	<0.001
NLR	0.95 (0.90–0.99)	0.03
Diabetes		
Yes	0.80 (0.69–0.91)	<0.001
No	Ref	–
Cerebrovascular disease		
Yes	0.82 (0.70–0.96)	0.014
No	Ref	–
Congestive heart failure		
Yes	0.79 (0.63–0.96)	0.007
No	Ref	–
Peripheral vascular disease		
Yes	0.78 (0.63–0.96)	0.02
No	Ref	–
Intervention group		
Allopurinol	Ref	–
Febuxostat	1.23 (1.08–1.40)	0.002

* χ^2 test = 576.75, df = 20, $P < 0.001$; Nagelkerke $R^2 = 0.171$; and C-index = 0.709. CI, confidence interval; NLR, neutrophil-lymphocyte ratio; OR, odds ratio.

In this analysis, we also observed that, of those fulfilling remission at year 1, 73.2% to 76.0% maintained their remission status in subsequent years. Similarly, of those participants who were in remission in year 6, 50% were also in remission in year 1. This implies that most people who are in remission early in treatment can maintain that status over a long period. Also, for those not in remission at year 1, 32.0% to 54.6% had fulfilled remission in subsequent years, which provides encouragement for the continuation of ULT in aiming for gout remission.

In this study, over the six years, >50% of participants were able to experience at least one episode of remission. In the first 2 years, those in the febuxostat group were significantly more

likely to achieve remission than those in the allopurinol group. This is primarily because of the fulfillment of the serum urate domain, which was seen more in the febuxostat group during years 1 and 2. It may be that the intensive serum urate lowering afforded by febuxostat is beneficial for earlier achievement of remission. The intensive urate lowering may have also contributed to the significantly higher odds of people in the febuxostat group fulfilling the tophus domain in year 6.

In this study, multiple baseline variables were independently associated with remission. In the multivariable analysis, febuxostat treatment remained significantly associated with increased odds of remission. Of the demographic variables, older age

(≥65 years) was associated with increased odds of remission. Non-White races (Black and “other”) had lower odds of remission, indicating that non-White populations are less likely to experience remission over time. Inequities in gout management and outcomes across different racial groups are well documented,^{16–18} and our results suggest that, in treatment aimed at gout remission, there needs to be clinical support tailored to the diverse backgrounds and needs of specific communities. Baseline variables associated with greater disease burden, such as longer disease duration, presence of tophus, higher serum urate concentration, and higher frequency of gout flares, were all associated with lower odds of gout remission. Participants with disease duration >5 years, presence of multiple tophi, serum urate concentration >0.54 mmol/L, and multiple flares in preceding years may require intensive treatment strategies to experience remission and additionally may require long periods of time to be able to achieve remission.¹⁵ Similarly, participants with comorbidities such as diabetes, cerebrovascular disease, congestive heart failure, and peripheral vascular disease may also require additional support to reach gout remission as these were other variables associated with lower odds of remission in the multivariable analysis.

This study had many strengths, including using a dataset that involved a large population of people with gout in a randomized controlled trial of ULT that had frequent visits assessing serum urate, gout flare, and tophus burden. Furthermore, the data were collected over multiple years, thus enabling the longitudinal analysis of gout remission over 6 years. A potential limitation of our analysis is the risk of overadjustment and the misinterpretation of confounder and modifier coefficients, as discussed by Westreich and Greenland.¹⁹ Although we carefully selected the variables and interpreted the results within the broader context, including the univariable analyses provided in the supplementary materials, we acknowledge that residual confounding may still be a concern. A key limitation of this study was the high rate of loss to follow-up, missing data, and study drug discontinuation, which may have influenced remission estimates. Our use of available case analysis, although a practical approach, may introduce bias through overestimation or underestimation of remission rates. Additionally, this approach may affect the validity and generalizability of our findings as participants with available data may not be fully representative of the entire study population. Also, the presence of cardiovascular disease was a key inclusion criterion for the CARES study and as such the results may not be generalizable to other populations of people with gout.

In conclusion, >50% of participants achieved remission at least once over 6 years. More participants receiving febuxostat achieved remission, reflected by faster initial urate lowering. We identified baseline predictors that highlight people with gout who may need more proactive and intensive management to achieve remission.

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AUTHOR CONTRIBUTIONS

All authors contributed to at least one of the following manuscript preparation roles: conceptualization AND/OR methodology, software, investigation, formal analysis, data curation, visualization, and validation AND drafting or reviewing/editing the final draft. As corresponding author, Dr Dalbeth confirms that all authors have provided the final approval of the version to be published and takes responsibility for the affirmations regarding article submission (eg, not under consideration by another journal), the integrity of the data presented, and the statements regarding compliance with institutional review board/Declaration of Helsinki requirements.

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