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Analysis of Gout Remission Definitions in a Randomized Controlled Trial of Colchicine Prophylaxis for People With Gout Initiating Allopurinol

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ABSTRACT. ***Objective.*** To investigate (1) the effect of colchicine prophylaxis on gout remission when commencing urate-lowering therapy (ULT), and (2) illness perceptions of people in remission using 2 definitions of gout remission.

Methods. Data from a 12-month double-blind placebo-controlled trial of 200 people with gout commencing allopurinol were analyzed. Participants were randomly assigned to prophylaxis with 0.5 mg daily colchicine or placebo for 6 months, followed by 6 months of additional follow-up. Gout remission was assessed using the 2016 preliminary definition or simplified definition without patient-reported outcomes. Illness perceptions were assessed using a gout-specific version of the Brief Illness Perception Questionnaire.

Results. In the first 6 months, few participants were in remission according to either the 2016 preliminary definition (3% for colchicine and 4% for placebo) or the simplified definition (7% for colchicine and 12% for placebo). In the second 6 months, after study drug (colchicine or placebo) discontinuation, fewer participants in the colchicine group than in the placebo group were in remission according to the 2016 preliminary definition (4% vs 14%, $P = 0.03$), and the simplified definition (14% vs 28%, $P = 0.02$). Participants fulfilling remission using either definition had more favorable perceptions about their gout symptoms and illness concerns, as well as consequences, when using the simplified definition.

Conclusion. Using either definition, 6 months of colchicine prophylaxis when initiating ULT does not provide an advantage in the fulfillment of gout remission. People fulfilling either definition report fewer symptoms, less concern about their gout, and, when using the simplified definition, are less affected by gout.

Key Indexing Terms: colchicine, gout, remission

Gout is a common inflammatory arthritis resulting from deposition of monosodium urate crystals in the joints and periarticular tissue.[1] Long-term management of gout with urate-lowering therapy (ULT), treating to a serum urate (SU) target < 0.36 mmol/L, prevents recurrent gout flares and progressive disease.[2]

In 2016, a preliminary definition for gout remission was described. The definition was as follows: absence of gout flares, SU < 0.36 mmol/L, absence of tophi, pain due to gout < 2 on a 10-cm visual analog scale (VAS), and patient global assessment (PtGA) of gout disease activity < 2 on a 10-cm VAS.[3] In a subsequent qualitative study examining patient perspectives of gout remission, patients indicated that the pain domain and PtGA domain may be unnecessary when defining gout remission.[4] Based on this, a simplified gout remission definition, which uses the same domains as the 2016 preliminary gout remission definition but does not include the patient-reported outcomes (PROs), has been assessed.[5] In a 2-year trial of intensive ULT for erosive gout, more people fulfilled the simplified definition, and fulfillment of either definition was associated with lower baseline monosodium urate volume measured by dual-energy computed tomography.[5]

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Gout flares are common during initiation of ULT.[6-8] For this reason, major rheumatology guidelines recommend antiinflammatory prophylaxis for 3 to 6 months when commencing ULT to reduce the frequency of gout flares.[9-11] We have recently reported a 12-month double-blind, placebo-controlled, randomized, noninferiority trial of people with gout commencing allopurinol with a "start-low go-slow" allopurinol dose escalation approach.[12] This previous study demonstrated that placebo was not noninferior to colchicine in prevention of gout flares in the first 6 months of the trial.[12] In the second 6 months of the trial, after stopping the study drug, gout flares rose in the colchicine group but not in the placebo group. Similar SU, tophus, and PROs were observed between the 2 groups. Herein, we report an analysis of this trial that aimed to investigate (1) the effect of colchicine prophylaxis on gout remission when commencing ULT, and (2) illness perceptions of people in remission, using the 2 definitions of gout remission.

METHODS

This paper reports an analysis of a 12-month double-blind, placebo-controlled, randomized noninferiority trial of people with gout recruited from primary and secondary care clinics in Christchurch and Auckland, New Zealand. The full methods and results of the trial have been reported in full (trial registration no.: ACTRN 12618001179224).[12] In brief, participants were included if they had gout according to the 2015 American College of Rheumatology (ACR)/European Alliance of Associations for Rheumatology (EULAR) criteria,[13] were ≥ 18 years old, had at least 1 self-reported gout flare in the preceding 6 months, met the ACR guidelines recommendation for initiating ULT,[10] and had an SU concentration of ≥ 0.36 mmol/L at screening. Ethical approval was obtained from the Health and Disability Ethics Committee, New Zealand (18/STH/156), and all participants provided written informed consent.

Participants were randomly assigned to colchicine 0.5 mg daily or placebo for 6 months, followed by a further 6 months of follow-up after study drug discontinuation. All participants commenced allopurinol with 50 mg daily (estimated glomerular filtration rate [eGFR] < 60 mL/min/1.73 m^2) or 100 mg daily (eGFR ≥ 60 mL/min/1.73 m^2), and doses were increased monthly by 50 mg or 100 mg daily until a SU concentration of < 0.36 mmol/L, or < 0.30 mmol/L for those with tophi, was maintained for 3 consecutive months. Allopurinol was continued indefinitely unless participants experienced an adverse event requiring discontinuation.[12]

Outcomes. After the baseline visit, participants attended 3-monthly follow-up visits with telephone assessments undertaken in the intervening months. Gout flares, defined as self-reported gout flares requiring treatment, were recorded at monthly intervals. SU, subcutaneous tophus count, PtGA, and pain were recorded at 3-monthly intervals. These outcomes that were reported at the follow-up visits were used to measure gout remission.

Gout remission using the 2016 preliminary definition (ie, absence of gout flares, absence of tophus, SU < 0.36 mmol/L, pain < 20 mm, PtGA < 20 mm on 0-100 mm scale[3]) and simplified definition (same domains without the PROs[4]) were assessed over 3-month and 6-month time frames. Supplementary Table S1 (available with the online version of this article) outlines the individual remission domains analyzed for fulfillment of the preliminary definition and simplified definition over these time periods. Neither the pain questionnaire nor the PtGA questionnaires used in the study were specific to gout.

Illness perceptions about gout were assessed using a gout-specific version of the Brief Illness Perception Questionnaire (BIPQ), which measured participant concerns, understanding, and emotional responses about gout. The BIPQ is a reliable and valid tool for assessing patients' beliefs and views about their illness,[14] and the gout-specific BIPQ has been used in prior gout research.[15-19] The questions specific to gout addressed consequences (how much gout affects the patient's life), timeline (how long the patient thinks gout will continue), personal control (how much control the patient has over their gout), treatment control (how much the patient's medication can control gout), identity (severity of gout symptoms), concern (how concerned the patient is about their gout), understanding (how well the patient feels they understand their gout), and emotional response (how much gout affects the patient emotionally). Each question was rated by patients on a 0-10 Likert scale, with higher scores indicating stronger endorsement of the question.

Statistical analysis. Demographics and clinical features were summarized using standard descriptive statistics including mean (SD), median (IQR), and count (%), as appropriate. Comparison of proportions between those fulfilling and not fulfilling the 2016 preliminary definition, simplified definition, and individual remission domains were analyzed using Pearson chi-square test for independent groups and McNemar test for paired data. Binary logistic regression was used to measure the association between these remission definitions and the colchicine and placebo group.

Cohen κ coefficient was used to assess the agreement between the 2016 preliminary definition and simplified definition in measuring gout remission. $\kappa < 0$ was considered as no agreement, 0-0.20 as slight agreement, 0.21-0.40 as fair agreement, 0.41-0.60 as moderate agreement, 0.61-0.80 as substantial agreement, and 0.81-1.0 as perfect agreement.[20] The percentage agreement described the observed proportion of all observations in agreement.

Using the general linear model algorithm, the BIPQ scores at month 12 were used to compare illness perception between those fulfilling and not fulfilling the 2016 preliminary definition and simplified definition during months 7-12, controlling for baseline BIPQ scores and treatment groups.

In the main trial, there were 24 participants who were lost to follow-up (13 in the colchicine group and 11 in the placebo group) and 2 participants who died (both in the colchicine group) during the study. In the remission analysis, missing data were addressed through multiple imputation using the fully conditional specification algorithm with predictive mean matching in SPSS. All statistical analyses were performed using SPSS software, version 28 (IBM Corp.) and GraphPad Prism software, version 9.3.1 (GraphPad). $P < 0.05$ was used to denote statistical significance.

RESULTS

Clinical features. Clinical features of the study participants are shown in Supplementary Table S2 (available with the online version of this article). Most participants were male, with a mean age of 56 years and a mean disease duration of 11 years. At baseline, the median number of gout flares in the preceding 6 months was 2, the mean SU concentration was 0.50 mmol/L, and a quarter of participants had subcutaneous tophi. The mean pain score was 13 mm, and the mean PtGA was 24 mm.

Effect of colchicine prophylaxis on gout remission throughout the study. In the first 6 months of the trial, 3% of participants in the colchicine group and 4% in the placebo group were in remission according to the 2016 preliminary definition (odds ratio [OR] 0.62, 95% CI 0.12-3.18, $P = 0.57$). Similarly, during this time period, 7% of participants in the colchicine group and 12% in the placebo group were in remission according to the simplified definition (OR 0.61, 95% CI 0.22-1.68, $P = 0.34$; Table 1).

In the second 6 months of the trial, after study drug discontinuation, fewer participants in the colchicine group (4%) were in remission according to the 2016 preliminary definition compared to those in the placebo group (14%; OR 0.29,

Table 1. Six-monthly fulfillment of the 2016 preliminary gout remission definition and the simplified gout remission definition according to randomized group.

Six-monthly Fulfillment of the 2016 Preliminary Definition	Colchicine, n = 100	Placebo, n = 100	OR (95% CI)[a]	*P*
Months 1-6	3 (3)	4 (4)	0.62 (0.12-3.18)	0.57
Months 7-12	4 (4)	14 (14)	0.29 (0.09-0.90)	0.03
Six-monthly Fulfillment of the Simplified Definition	**Colchicine, n = 100**	**Placebo, n = 100**	**OR (95% CI)[a]**	***P***
Months 1-6	7 (7)	12 (12)	0.61 (0.22-1.68)	0.34
Months 7-12	14 (14)	28 (28)	0.41 (0.20-0.85)	0.02

[a] Participants in placebo group were used as the reference. OR: odds ratio.

95% CI 0.09-0.90, $P = 0.03$; Table 1). Similarly, fewer participants in the colchicine group (14%) were in remission according to the simplified definition during this time period compared to those in the placebo group (28%; OR 0.41, 95% CI 0.20-0.85, $P = 0.02$; Table 1).

Effect of colchicine prophylaxis on individual remission domains throughout the study. Individual remission domains were examined to understand the reasons for differences in fulfillment of the remission definitions between the 2 groups. There were no differences in the SU, tophus, and pain domains between the colchicine and placebo groups (Figure 1; Supplementary Figure S1, available with the online version of this article).

In the first 6 months of the trial, there were no differences between the colchicine group and placebo group in fulfillment of the gout flares domains, but in the second 6 months of the trial, after study drug discontinuation, fewer participants in the colchicine group (23%) fulfilled the gout flares domain compared to those in the placebo group (41%; $P = 0.01$; Figure 1).

In the first 6 months of the trial, fewer participants in the colchicine group (35%) fulfilled the PtGA domain compared to those in the placebo group (49%; $P = 0.04$). Similarly, in the second 6 months of the trial, fewer participants in the colchicine group (35%) fulfilled the PtGA domain compared to the placebo group (51%; $P = 0.02$; Figure 1).

Agreement between the 2016 preliminary definition and simplified definition. There were significantly more people in remission at either timepoint according to the simplified definition ($P < 0.001$; Figure 2). Cohen κ analysis showed moderate agreement between the 2 definitions in the first 6 months of the trial (κ 0.51, 95% CI 0.28-0.75, $P < 0.001$), with percentage agreement of 94% (95% CI 90-97%). During the second 6 months of the trial, there was also moderate agreement between the definitions (κ 0.54, 95% CI 0.39-0.70, $P < 0.001$; percentage agreement 88%, 95% CI 83-92%).

Illness perceptions of people in gout remission. Compared to participants who were not in gout remission according to the 2016 preliminary definition, those in remission reported fewer gout symptoms (lower identity belief scores; $P = 0.04$) and were less concerned about gout (lower concern belief scores; $P = 0.01$) at the month 12 visit (Table 2). There were no significant differences in other BIPQ items.

Similarly, compared to participants who were not in remission according to the simplified definition, those in remission reported fewer symptoms (lower identity belief scores; $P = 0.002$), and were less concerned about gout (lower concern belief scores; $P = 0.002$) at the month 12 visit (Table 3). Additionally, those in remission according to the simplified definition felt their life was less affected by gout (lower consequence belief scores; $P = 0.002$). There were no significant differences in other BIPQ items.

DISCUSSION

For people with gout, an important treatment goal is remission.[4] Absence of gout flares is a key domain contributing to both the 2016 preliminary gout remission definition and the simplified gout remission definition. The use of antiinflammatory prophylaxis when commencing ULT is recommended to reduce the risk of gout flares. In this study, we investigated the effect of colchicine prophylaxis on gout remission when commencing ULT. We found that colchicine prophylaxis for 6 months when commencing allopurinol does not provide an advantage for reaching gout remission, using either definition, and lower rates of gout remission were observed after stopping colchicine due to higher frequency of gout flares. We also investigated illness perceptions of people in remission using either definition. Participants in gout remission had more favorable perceptions of their gout. Specifically, they experienced fewer symptoms of gout, fewer concerns about gout, and, when using the simplified definition, less impact of gout on their lives.

For both groups, remission was very uncommon in the first 6 months of starting ULT, and use of colchicine prophylaxis did not lead to more participants in remission using either definition over this period. Participants in this study had a mean disease duration of 11 years, and 25% of participants had tophaceous gout. Prior research has shown that patients with tophi are less likely to achieve remission after starting ULT,[21] and it is possible that remission rates may have been

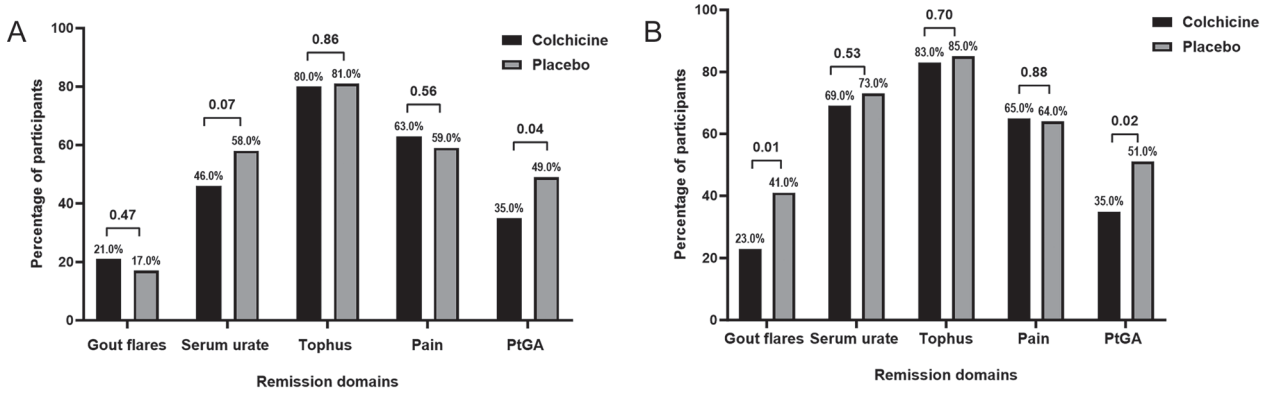

Figure 1. Fulfillment of individual domains by intervention over the (A) first 6 months and (B) last 6 months. PtGA: patient global assessment.

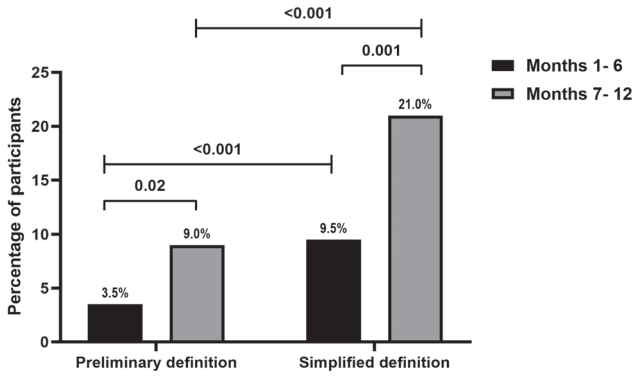

Figure 2. Fulfillment of remission definitions over 6-monthly periods.

higher in patients with earlier disease duration and less severe disease.

In the last 6 months of the trial, after discontinuation of the study drug, fewer participants in the colchicine group were in remission using either definition compared to those in the placebo group. An increase in gout flares after discontinuing colchicine contributed to the lower rates of remission in the colchicine group. Gout management guidelines recommend the use of antiinflammatory prophylaxis for 3 to 6 months when commencing ULT[10]; however, it may be that colchicine prophylaxis for longer than 6 months is needed for the fulfillment of gout remission, particularly as it only addresses the gout flares component of gout remission and other components, such as tophus reduction, can take longer to resolve. Other trials have also reported an increase in gout flares after stopping antiinflammatory prophylaxis when used for shorter

Table 2. Comparison of month 12 BIPQ scores between those who fulfilled and did not fulfill the 2016 preliminary gout remission definition in the final 6 months of the trial (months 7-12).

Belief Type	BIPQ Item[a]	Fulfilled, n = 18, mean (95% CI)	Not Fulfilled, n = 182, mean (95% CI)	Mean Difference (95% CI)	*P*
Consequence	How much does gout affect your life? (10 = severely affects life)	0.86 (−0.53 to 2.26)	2.18 (1.75 to 2.63)	1.32 (−0.10 to 2.75)	0.07
Timeline	How long do you think your gout will continue? (10 = will continue forever)	8.78 (6.84 to 10.73)	7.58 (6.99 to 8.16)	−1.20 (−3.22 to 0.80)	0.25
Personal control	How much control do you feel you have over your gout? (10 = extreme amount)	9.02 (7.86 to 10.19)	8.12 (7.70 to 8.54)	−0.90 (−2.12 to 0.32)	0.15
Treatment control	How much do you think your treatment can help your gout? (10 = extremely helpful)	8.96 (7.95 to 9.98)	8.81 (8.42 to 9.21)	−0.15 (−1.21 to 0.91)	0.77
Identity	How much do you experience symptoms from your gout? (10 = many severe symptoms)	0.89 (−0.21 to 2.00)	2.10 (1.72 to 2.50)	1.21 (0.05 to 2.37)	0.04
Concern	How concerned are you about your gout? (10 = extremely concerned)	1.20 (−0.34 to 2.73)	3.40 (2.84 to 3.96)	2.20 (0.63 to 3.77)	0.01
Understanding	How well do you feel you understand your gout? (10 = very clearly)	8.70 (7.71 to 9.69)	8.35 (8.00 to 8.71)	−0.35 (−1.38 to 0.67)	0.48
Emotional response	How much does your gout affect you emotionally? (10 = extremely affected)	0.97 (−0.39 to 2.33)	2.10 (1.65 to 2.55)	1.13 (−0.22 to 2.48)	0.08

[a]Each question was rated on a 0-10 Likert scale. BIPQ: Brief Illness Perception Questionnaire.

Table 3. Comparison of month 12 BIPQ scores between those who fulfilled and did not fulfill the simplified gout remission definition in the final 6 months of the trial (months 7-12).

Belief Type	BIPQ Item[a]	Fulfilled, n = 42, mean (95% CI)	Not Fulfilled, n = 158, mean (95% CI)	Mean Difference (95% CI)	*P*
Consequence	How much does gout affect your life? (10 = severely affects life)	0.84 (−0.01 to 1.70)	2.39 (1.91 to 2.87)	1.55 (0.61 to 2.48)	0.002
Timeline	How long do you think your gout will continue? (10 = will continue forever)	8.03 (6.94 to 9.14)	7.49 (6.84 to 8.15)	−0.54 (−1.77 to 0.68)	0.39
Personal control	How much control do you feel you have over your gout? (10 = extreme amount)	8.71 (7.94 to 9.48)	8.07 (7.60 to 8.53)	−0.64 (−1.50 to 0.22)	0.15
Treatment control	How much do you think your treatment can help your gout? (10 = extremely helpful)	9.07 (8.38 to 9.75)	8.77 (8.33 to 9.20)	−0.30 (−1.04 to 0.44)	0.44
Identity	How much do you experience symptoms from your gout? (10 = many severe symptoms)	0.80 (−0.01 to 1.62)	2.29 (1.86 to 2.71)	1.49 (0.60 to 2.37)	0.002
Concern	How concerned are you about your gout? (10 = extremely concerned)	1.61 (0.53 to 2.69)	3.59 (2.97 to 4.20)	1.98 (0.83 to 3.12)	0.002
Understanding	How well do you feel you understand your gout? (10 = very clearly)	8.65 (7.97 to 9.33)	8.35 (7.96 to 8.74)	−0.30 (−1.04 to 0.45)	0.43
Emotional response	How much does your gout affect you emotionally? (10 = extremely affected)	1.29 (0.42 to 2.16)	2.19 (1.70 to 2.69)	0.90 (−0.06 to 1.86)	0.07

[a] Each question was rated on a 0-10 Likert scale. BIPQ: Brief Illness Perception Questionnaire.

periods, which could again influence gout remission when commencing ULT.[8,22]

Our present study also showed that people in remission according to the 2016 preliminary definition reported fewer gout symptoms and were less concerned about their gout. When remission was defined using either the 2016 preliminary definition or the simplified definition, participants reported fewer gout symptoms, were less concerned about their gout, and, when using the simplified definition, also felt less affected by gout. This finding illustrates that, in terms of defining gout remission, the simplified definition has high construct validity. The value of PROs in defining remission has been greatly debated for other rheumatic diseases.[23] However, our study suggests that a definition without the PROs may be more sensitive in identifying people in gout remission. This is an important finding as the simplified definition may be more feasible for use in both clinical practice and research settings. It is also important to note that the simplified remission definition could be overestimating the rates of remission, and that the exclusion of pain and PtGA may mean some participants are incorrectly classified as being in gout remission. Further analysis could aim to evaluate alternative definitions for gout remission including introducing more lenient thresholds for the PROs. This approach has recently been taken with definitions of rheumatoid arthritis remission, with a change of the PtGA of disease activity threshold to 2 cm from 1 cm.[24]

Strengths of this study include the double-blind, randomized approach, the measurement of Outcome Measures in Rheumatology (OMERACT) core outcome domains, and the 6-month follow-up after discontinuation of colchicine/placebo interventions. A potential limitation of this study is its 12-month study duration, which did not enable the assessment of gout remission over longer follow-up. Another limitation of this study is the absence of gout-specific pain and PtGA questionnaires. The PtGA domain may have been influenced by more adverse events in the colchicine group,[12] resulting in lower proportions of participants in the colchicine group fulfilling the PtGA domain compared to those in the placebo group.

In summary, 6 months of colchicine prophylaxis did not provide an advantage in achieving gout remission when initiating ULT, and it decreased the odds of gout remission after colchicine discontinuation. People in remission, using either the 2016 preliminary definition or simplified definition, report fewer symptoms, have less concern about their gout, and, when using the simplified definition, are less affected by gout. The simplified definition has high construct validity, feasibility, and sensitivity for identifying people in remission and may be sufficient to define gout remission.

ONLINE SUPPLEMENT

Supplementary material accompanies the online version of this article.

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