

Illness Perceptions in Patients With Gout and the Relationship With Progression of Musculoskeletal Disability

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Objective. Illness perceptions are key determinants of behavior directed at managing disease. Although suboptimal disease management has been reported in patients with gout, patients' perceptions of illness have not been systematically studied. The aim of this study was to examine illness perceptions in patients with gout.

Methods. A total of 142 patients with gout for <10 years were recruited from primary and secondary care settings. Participants completed a gout-specific Brief Illness Perception Questionnaire, questionnaires about medication beliefs and adherence to urate-lowering therapy (ULT), and had a comprehensive assessment of gout disease activity. Serum urate, flare frequency, and Health Assessment Questionnaire (HAQ-II) scores were recorded at baseline and after 1 year.

Results. Patients viewed gout as a chronic condition that was responsive to treatment but not strongly influenced by personal actions. Overall, gout was seen as having a moderate impact on their life. Most patients believed that gout was caused by dietary factors. Adherence to ULT was positively associated with a greater perceived understanding of gout and inversely associated with perceived severity and consequences of disease. Of the clinical factors assessed, pain scores were most strongly associated with negative illness perception scores at baseline. Baseline illness perception scores (perceived severity of symptoms and consequences, lower personal and treatment control) predicted worsening musculoskeletal disability at 1 year as determined by the HAQ-II. This relationship was independent of baseline disability scores.

Conclusion. Negative or pessimistic views about gout are associated with poorly controlled disease, lower adherence to ULT, and progression of musculoskeletal disability in patients with gout.

INTRODUCTION

Gout is a prevalent disease of purine metabolism characterized by intermittent self-limiting episodes of acute arthritis. In the presence of persistent hyperuricemia, chronic tophaceous disease may also occur. Management of gout includes lifestyle changes such as weight reduction

and specific dietary modifications (avoidance of purine rich foods, alcohol, and fructose-containing beverages). Long-term urate-lowering therapy is also recommended for most patients with gout, with the goal of therapy to reduce the serum urate concentrations below 0.36 mmol/liter (6 mg/dl) (1). Persistent reduction in serum urate concentrations below this target leads to dissolution of urate crystals, prevention of gout flares, and regression of tophi (2–4). Although the pathophysiology of gout is well understood, and effective treatments are available, management of the disease is frequently poor (5). Studies from many countries have shown that serum urate monitoring is often inadequate and adherence to long-term urate-lowering therapy is low (<50%) (6–8). Although health provider actions are likely to contribute to this suboptimal management (9,10), patient attitudes and behavior may also play a role.

When individuals are diagnosed with an illness, they develop an organized pattern of beliefs about their disease. Illness perceptions are key determinants of behavior directed at managing disease and have been associated with outcome in chronic diseases (11). A major line of research

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Significance & Innovations

- Although poor disease management has been widely reported in patients with gout, patients' perceptions of the disease and beliefs about medications have not been studied. This longitudinal study is the first to systematically examine illness perceptions in patients with gout.
- The key findings are that negative or pessimistic views about gout are associated with poorly controlled disease, lower adherence to urate-lowering therapy, and progression of musculoskeletal disability in patients with gout.
- The finding that patients perceive gout as a disease caused by external dietary factors, but not strongly influenced by personal actions, provides new information that will guide patient education and engagement in gout management.
- These data raise the possibility that an individualized intervention program designed to change behavior by altering patients' illness perceptions may improve outcome in patients with gout.

in this area is Leventhal's self-regulatory model of how illnesses and other health threats are conceptualized by patients (12). Patients' perceptions of illness comprise 5 main components: identity, cause, timeline, consequences, and control (12). Illness perceptions are dynamic and modification of negative illness perceptions has been shown to improve outcome in some chronic illnesses (13–16). Although poor disease management has been reported in patients with gout, patients' perceptions of the disease have not been systematically studied. The aims of this study were to determine the illness perceptions in patients with gout, to understand how patients' perceptions are related to medication beliefs and adherence to urate-lowering therapy, and to examine the influence of illness perceptions on disease outcomes over time.

PATIENTS AND METHODS

A total of 142 patients with gout for <10 years were recruited by community advertising and through primary and secondary care clinics in Auckland and Wellington, New Zealand. As in other regions of the world, gout management is frequently suboptimal in New Zealand and treatment targets are often not achieved in patients with gout (17,18). The inclusion criteria for this study were a previous physician diagnosis of acute gout as defined by the Wallace classification for acute gout (19), a first attack of gout within the last 10 years, and the ability to complete forms in English and provide written informed consent. The New Zealand Multi Regional Ethics Committee approved this study.

Participants attended a baseline study visit, which included a comprehensive clinical assessment. The following data were recorded: demographic data (age, sex, eth-

nicity), gout history (confirmation of diagnosis, disease duration, frequency of gout flares, gout treatments), medical history, examination (including tender joint count [68 assessed], swollen joint count [66 assessed], and tophus count), questionnaires (including the Health Assessment Questionnaire [HAQ-II], pain visual analog score [100-mm scale], Brief Illness Perception Questionnaire [B-IPQ], and a medication adherence score related to urate-lowering therapy), laboratory tests (including serum urate, creatinine, and C-reactive protein). After 1 year, further information was obtained, including frequency of gout flares and HAQ-II responses using a mail survey. Repeat blood tests were also obtained in community laboratories at 1 year for serum urate and creatinine.

Illness perceptions were determined by a gout-specific B-IPQ, which assessed the 5 main illness perception dimensions, as well as items measuring the patient's concern, understanding, and emotional response to the illness. The specific items in the scale were 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 his or her disease), treatment control (how much the patient's medication can control gout), identity (severity of gout symptoms), concern (how concerned the patient is about his or her gout), understanding (how well the patient feels he/she understands their gout), and emotional response (how much gout affects the patient emotionally). Each dimension was measured by a single item rated by patients on a 0–10 Likert scale, with higher scores indicating stronger endorsement of that item (20). Patients were also asked to report the factors believed to cause their gout. Research demonstrates that the B-IPQ has acceptable reliability and good concurrent, predictive, and discriminant validity in a range of chronic illnesses (20).

Patients completed the 10-item HAQ-II in English. This self-report questionnaire examines 10 key domains of activities of daily living. Each domain is scored 0–3, with the sum of all domains divided by 10 to provide a HAQ-II score ranging from 0 (no disability) to 3 (severe disability) on an ordinal scale. This questionnaire has been shown to be a valid measure of musculoskeletal disability in patients with gout (21–23).

A 9-item questionnaire based on the Medication Adherence Report Scales was used to assess adherence to urate-lowering therapy. This is a self-report measure of medication adherence. This questionnaire has been shown to be a reliable indicator of nonadherence to prescribed long-term medication regimens (24). In addition, beliefs about urate-lowering therapy were assessed using a 2-item questionnaire measuring the patient's perception of the need to take the medication and concerns about taking the medication, and measured by a single item scored on a 0–10 Likert scale, with higher scores indicating stronger endorsement of that item.

Data were analyzed using SPSS software. Medians with ranges and percentages were used to describe the clinical characteristics of participants. Spearman's correlations were used to describe the associations between variables. Differences in B-IPQ scores based on ethnicity and sex were analyzed using 2-way analysis of variance with Bon-

Table 1. Clinical characteristics*

	Baseline data, all patients (n = 142)	Baseline data, year 1 cohort (n = 132)	Followup data, year 1 cohort (n = 132)
Age, years	57 (19–85)	57 (21–85)	58 (20–86)
Male, no. (%)	111 (78)	100 (76)	–
Ethnicity, no. (%)			
European	71 (50)	68 (52)	–
Māori	29 (20)	27 (20)	–
Pacific	27 (19)	23 (17)	–
Other	16 (11)	14 (11)	–
Occupation, no. (%)			
Working	75 (53)	73 (55)	–
Retired	38 (27)	42 (32)	–
Beneficiary	29 (20)	17 (13)	–
Age at first episode, years	50 (18–82)	51 (18–82)	–
Disease duration	5 (0.25–10)	5 (0.25–10)	6 (1–11)
No. of flares in preceding 3 months	1 (0 to constant)	1 (0 to constant)	0 (0 to constant)
Days off work in preceding 3 months	0 (0–90)	0 (0–90)	0 (0–90)
Microscopically proven gout, no. (%)	38 (27)	32 (24)	–
Urate-lowering therapy, no. (%)	105 (74)	97 (73)	–
Patients with tophi, no. (%)	35 (25)	32 (24)	–
Total number of tophi	0 (0–14)	0 (0–14)	–
Tender joint count	1 (0–10)	1 (0–10)	–
Swollen joint count	0 (0–30)	0 (0–30)	–
Serum urate (mmoles/liter)	0.41 (0.15–0.74)	0.41 (0.15–0.74)	0.38 (0.14–0.86)
Serum creatinine (μmoles/liter)	97 (45–729)	94.5 (45–729)	97.5 (53–776)
C-reactive protein (mg/liter)	2.6 (1–169)	2.8 (1–169)	–
Pain visual analog score (mm)	8.8 (0–100)	9.0 (0–100)	–
HAQ-II score	0.4 (0–3.0)	0.4 (0–3.0)	0.25 (0–2.8)

* Values are the median (range) unless indicated otherwise. HAQ-II = Health Assessment Questionnaire II.

ferroni post hoc tests. Stepwise multiple regression analysis was used to determine the independent clinical variables associated with illness perception scores and predictors of outcome after 1 year. The key measures of outcome were prespecified as flare frequency, serum urate, and disability as assessed by the HAQ-II. All tests were 2-tailed and *P* values less than 0.05 were considered statistically significant.

RESULTS

Baseline characteristics. The clinical characteristics are shown in Table 1. There were 142 patients recruited into the study and 1-year followup data were available for 132 (93%) of these patients. Ten participants did not provide followup data; 2 died and 8 were lost to followup. The patients were predominantly middle-aged men with a wide range in disease severity as indicated by gout flare frequency, serum urate concentration, and HAQ-II score. There was no difference in baseline clinical characteristics between the entire group (n = 142) and those with available data at 1 year (n = 132). There were no significant differences in measures of gout severity (flare frequency, serum urate concentration, HAQ-II score) between the baseline and 1-year time points (Table 1). The median (range) change in HAQ-II score over 1 year was 0 (–1.8 to 2.0).

Illness perception scores. There was a large variation in patients' perceptions of the illness and perceived ability to control their symptoms (Table 2). Generally, patients viewed gout as a chronic condition that was responsive to treatment but not strongly influenced by personal actions. The majority believed they had a good understanding of their illness. Overall, gout was seen as having a moderate impact on their life. The majority of patients believed gout was caused by external factors such as dietary intake or alcohol use, and medical comorbidities were less frequently reported as the major cause of disease. For example, of the 36 (out of 142) patients on diuretic therapy, 5 (14%) reported diuretic use or medication as the cause of their disease and 16 (44%) reported diet or alcohol as the main cause. There were no differences in B-IPQ scores between men and women (data not shown). Compared with non-Polynesian patients, Māori and Pacific patients reported higher scores for consequences of disease (3.7 versus 6.2; *P* < 0.001), identity (4.8 versus 6.4; *P* < 0.05), concern (6.0 versus 8.2; *P* < 0.001), and emotional response (3.8 versus 6.3; *P* < 0.001).

Relationships between components of illness perception. Analysis of the interrelationships between the B-IPQ items showed a strong relationship between the perceived severity of gout symptoms (identity) and consequences of disease (Table 3). Patients with greater concern about gout had higher identity and consequence scores. Greater emo-

Table 2. Summary of illness perception scores at baseline

	Mean ± SD or no. (%)
Brief Illness Perception Questionnaire item (n = 142)	
Consequences (10 = severely affects life)	4.7 ± 3.4
Timeline (10 = will continue forever)	7.2 ± 3.4
Personal control (10 = extreme amount)	5.7 ± 3.1
Treatment control (10 = extremely helpful)	7.7 ± 2.9
Identity (10 = many severe symptoms)	5.4 ± 3.1
Concern (10 = extremely concerned)	6.9 ± 3.1
Understanding (10 = very clearly)	7.2 ± 2.7
Emotional response (10 = extremely affected)	4.8 ± 3.6
Beliefs about and adherence to urate-lowering therapy (n = 105)	
Need for urate-lowering therapy (10 = absolutely essential)	8.5 ± 2.4
Concern about urate-lowering therapy (10 = extremely concerned)	4.5 ± 3.9
Medication adherence score (45 = highly adherent)	39.8 ± 6.8
Most important factor believed to cause gout (n = 142)	
Diet (general)	27 (19)
Unknown	23 (16)
Alcohol intake	22 (15)
Seafood intake	20 (14)
Genetic risk	12 (8.5)
Joint trauma/injury	8 (5.6)
Diuretic use	6 (4.2)
Kidney disease	5 (3.5)
Stress	4 (2.8)
Medications (other than diuretics)	3 (2.1)
Medical conditions (other than kidney disease)	3 (2.1)
Red meat intake	3 (2.1)
Weight	3 (2.1)
Dehydration	2 (1.4)
Sugar-sweetened drinks	1 (0.7)

tional response to gout was strongly associated with the perceived severity of gout symptoms (identity), consequences, and concern regarding the disease. Personal control scores correlated highly with treatment control scores. Both personal and treatment control scores were positively associated with perceived understanding of gout and negatively associated with identity, consequences, and emotional response scores.

Relationships between illness perceptions, beliefs about urate-lowering therapy, and adherence to urate-lowering therapy. Patients receiving urate-lowering therapy reported a high level of need for these medications (Table 2). Overall, there was a moderate concern about taking these

medications, with a wide range of responses between patients (Table 2). Adherence scores were high in the group overall (Table 2) and, in patients taking urate-lowering therapy, serum urate inversely correlated with adherence scores ($r = -0.33$, $P = 0.003$).

Patients reporting greater understanding of their illness also reported a higher need for urate-lowering therapy, less concern about this medication, and greater adherence (Table 4). Patients with lower adherence to urate-lowering therapy reported more severe symptoms and consequences due to their gout. Concern regarding urate-lowering therapy was also associated with greater symptoms scores and less ability to control the disease through personal actions (Table 4).

Table 3. Relationships between B-IPQ items*

B-IPQ item	Timeline	Personal control	Treatment control	Identity	Concern	Understanding	Emotional response
Consequences	0.32†	-0.42†	-0.31†	0.72†	0.59†	-0.08	0.65†
Timeline		-0.05	-0.05	0.20‡	0.19‡	0.04	0.14
Personal control			0.58†	-0.41†	-0.26§	0.34†	-0.44†
Treatment control				-0.28§	-0.09	0.32†	-0.20‡
Identity					0.51†	-0.15	0.53†
Concern						0.05	0.62†
Understanding							-0.14

* Values are the Spearman's correlation coefficient (r). B-IPQ = Brief Illness Perception Questionnaire.
† $P < 0.001$.
‡ $P < 0.05$.
§ $P < 0.01$.

B-IPQ item	Need for urate-lowering therapy	Concern about urate-lowering therapy	Adherence to urate-lowering therapy
Consequences	0.15	0.18	-0.25†
Timeline	0.14	0.16	-0.01
Personal control	0.06	-0.25†	0.19
Treatment control	0.18	-0.14	0.13
Identity	0.10	0.27‡	-0.20†
Concern	0.20†	0.37§	-0.09
Understanding	0.21‡	-0.28‡	0.32‡
Emotional response	0.17	0.32‡	-0.26‡

* B-IPQ = Brief Illness Perception Questionnaire.
 † $P < 0.05$.
 ‡ $P < 0.01$.
 § $P < 0.001$.

Clinical variables associated with components of illness perception. Analysis of each B-IPQ item showed that a number of clinical factors were independently associated with components of illness perception at baseline (Table 5). Pain was independently associated with 5 of the 8 illness perception items (consequences, personal control, identity, concern, and emotional response). Other measures of gout disease severity, such as serum urate, flare frequency, and number of tophi, were also independently associated with illness perception scores. Disease duration was the only clinical factor independently associated with the belief that gout would continue for a long time (timeline item). No clinical factors were independent predictors of perceived understanding of disease. Even after adjusting for measures of disease severity, Māori or Pacific ethnicity

was associated with higher consequences, concern, and emotional response scores.

Relationship between baseline B-IPQ scores and changes in gout severity measures after 1 year. There was no relationship observed between baseline B-IPQ scores and change in serum urate or flare frequency at 1 year (data not shown). However, baseline illness perception item scores (consequences, personal control, treatment control, and identity) predicted change in musculoskeletal disability at 1 year, as determined by the HAQ-II (Table 6). In this analysis, worsening HAQ-II scores were associated with a higher perceived severity of symptoms and consequences of disease, and lower personal and treatment control scores at baseline. The relationship between baseline ill-

Dependent variable	Predictors	Standardized β	Partial R^2	P	Model
Consequences	Pain score	0.44	0.26	< 0.001	Adjusted $R^2 = 0.39$, $F = 20.6$, $P < 0.0001$
	Serum urate	0.25	0.11	0.002	
	Flare frequency	0.16	0.03	0.044	
	Māori/Pacific ethnicity	0.16	0.02	0.047	
Timeline	Disease duration	0.26	0.07	0.004	Adjusted $R^2 = 0.06$, $F = 8.5$, $P = 0.004$
Personal control	Pain score	-0.29	0.15	0.001	Adjusted $R^2 = 0.20$, $F = 10.9$, $P < 0.0001$
	Number of tophi	-0.18	0.04	0.029	
	Flare frequency	-0.18	0.03	0.039	
Treatment control	Tender joint count	-0.29	0.10	0.001	Adjusted $R^2 = 0.15$, $F = 11.4$, $P < 0.0001$
	Flare frequency	-0.26	0.07	0.003	
Identity	Pain score	0.50	0.24	< 0.001	Adjusted $R^2 = 0.31$, $F = 27.9$, $P < 0.0001$
	Serum urate	0.28	0.08	< 0.001	
Concern	Māori/Pacific ethnicity	0.30	0.11	< 0.001	Adjusted $R^2 = 0.16$, $F = 12.8$, $P < 0.0001$
	Pain score	0.26	0.06	0.003	
Understanding	Nil	-	-	-	-
Emotional response	Pain score	0.28	0.12	0.001	Adjusted $R^2 = 0.26$, $F = 9.4$, $P < 0.0001$
	Māori/Pacific ethnicity	0.21	0.08	0.010	
	Flare frequency	0.18	0.03	0.039	
	Age	-0.17	0.03	0.032	
	Disease duration	0.16	0.02	0.048	

* Variables included in models: age, sex, ethnicity, disease duration, flare frequency, tender joint count, swollen joint count, number of tophi, serum urate, C-reactive protein, and pain score.

Table 6. Stepwise linear regression analysis of baseline factors independently associated with change in the HAQ-II score after 1 year*

Model	Dependent variable	Predictors	Standardized β	Partial R^2	P	Model
1	Change in HAQ-II score	Baseline HAQ-II score	-0.60	0.20	< 0.0001	Adjusted $R^2 = 0.29$, F = 10.8, $P < 0.0001$
		Age	0.30	0.05	0.007	
		B-IPQ consequences score	0.29	0.08	0.008	
2	Change in HAQ-II score	Baseline HAQ-II score	0.53	0.20	< 0.0001	Adjusted $R^2 = 0.27$, F = 9.6, $P < 0.0001$
		Age	0.25	0.05	0.02	
		B-IPQ personal control score	-0.23	0.05	0.03	
3	Change in HAQ-II score	Baseline HAQ-II score	-0.47	0.19	< 0.0001	Adjusted $R^2 = 0.22$, F = 10.9, $P < 0.0001$
		B-IPQ treatment control score	-0.24	0.05	0.03	
4	Change in HAQ-II score	Baseline HAQ-II score	-0.53	0.20	< 0.0001	Adjusted $R^2 = 0.26$, F = 9.5, $P < 0.0001$
		Age	0.23	0.05	0.03	
		B-IPQ identity score	0.22	0.05	0.04	

* Variables included in models: age, sex, ethnicity, baseline Health Assessment Questionnaire (HAQ-II) score, adherence score, and Brief Illness Perception Questionnaire (B-IPQ) item score.

ness perception scores and change in HAQ-II scores was independent of baseline HAQ-II scores (Table 6). Within these models, baseline HAQ-II scores were the strongest independent predictor of change in HAQ-II scores, with baseline illness perception scores contributing an additional 5–8% to the models. Other illness perception item scores (timeline, concern, understanding, and emotional response) at baseline did not predict change in disability scores (data not shown).

DISCUSSION

This study has explored illness perceptions in patients with gout of <10 years's duration. Overall, gout was perceived as a chronic condition that can be managed with medical treatments. The majority of patients identified external dietary factors as the major cause of their disease, rather than less modifiable factors such as genetic risk, concomitant medical problems (such as renal impairment), or diuretic use. Despite beliefs that gout is caused primarily through diet and alcohol intake, patients did not perceive that gout was strongly influenced by their personal actions. Consistent with studies in other chronic illnesses (25,26), we have identified relationships between adherence to treatment and illness perception in patients with gout. Our data indicate that lower understanding about disease and higher emotional response, perceived severity, and consequences of disease are associated with lower adherence to urate-lowering therapy. The relationships between perceived understanding of disease, medication beliefs, and adherence scores suggest that interventions that target understanding of gout may reduce concern about urate-lowering therapy and improve adherence.

This study has highlighted aspects of gout that are associated with patients' perception of illness. High pain scores were most strongly and consistently associated with negative illness perceptions (including higher perceived severity of disease, concern, emotional response, and lower perceived personal control). This finding is in accordance with recent qualitative work, also identifying

pain as a central concern to patients experiencing gout (27). The episodic and unpredictable nature of acute gout is highlighted by the identification of higher flare frequency as a factor affecting patient perception of poor treatment and personal control of gout. The observation that serum urate concentration is associated with the perceived impact of disease and severity of symptoms provides further biologic validity to the results.

This study has identified some differences between ethnic groups in terms of their perceptions of gout. In particular, Māori and Pacific patients have a more negative view of their illness, perceiving gout as having greater consequences and reporting higher concern and emotional response to the disease independent of measures of gout disease severity. Māori and Pacific people have the highest reported rates of gout worldwide, with early onset of severe disease (28,29). It is possible that Māori and Pacific patients have different views about gout based on their own experience of disease and also through experiencing the impact of severe gout within their families and communities. Recent qualitative research has highlighted the impact of gout on family members and the role of community perceptions about gout in directing patient behavior (27).

Consistent with previous reports in other musculoskeletal diseases (13,14,30), illness perceptions at baseline predicted changes in musculoskeletal disability in this study of patients with gout. Although not all items of illness perception predicted change, the perceived severity and impact of gout, and the perceived ability to control the disease through treatments or personal actions did predict disability outcomes in these patients. These longitudinal data have implications for patient education and raise the possibility that interventions that specifically address illness perception might have an impact on clinically important outcomes in patients with gout. Further research identifying health outcomes of concern for patients with gout will assist in developing effective therapeutic and education strategies.

This study has a number of potential limitations. Partic-

ipants volunteered for the study through advertising in the community and in primary and secondary care clinics. In contrast to previous studies of patients with gout, the reported adherence to therapy was high in these patients. It is conceivable that those individuals who volunteer for such a study have different illness perceptions, medication beliefs, and adherence behaviors compared with those who do not volunteer. However, a wide recruitment strategy was employed to ensure that patients with varying disease experiences were included within the study. A further limitation may be the recruitment of patients with a disease duration of <10 years. Illness perceptions may change over time, and these changes may be particularly relevant in a disease such as gout, where early disease is characterized by recurrent self-limiting flares, and long-standing disease leads to tophi, bone erosion, and chronic gouty arthropathy. However, there was a large variation in disease severity in this study, and 25% of patients had subcutaneous tophi. To date, we have not assessed changes in illness perception over time; this will be a focus of further work in the ongoing longitudinal study. Many of the patients in this study were of Māori or Pacific ethnicity. This may limit the general applicability of this study as some differences in illness perception were observed between different ethnic groups. However, the regression analyses identified a number of clinical factors associated with negative illness perceptions independent of ethnicity. Therefore, we believe that these results are of general relevance. Confirmation of our findings in other populations will be of interest.

In summary, negative or pessimistic views about gout are associated with poorly controlled disease, lower adherence to urate-lowering therapy, and development of musculoskeletal disability in patients with gout. Randomized trials have shown that programs designed to modify patients' perceptions of illness and treatments improve adherence and other outcomes in diseases such as asthma and ischemic heart disease (15,16,31). Our data raise the possibility that an individualized intervention program designed to change behavior by altering patients' illness perceptions may improve outcome in patients with gout.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Dalbeth had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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