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Patient Perspectives on Gout and Gout Treatments: A Patient Panel Discussion That Informed the 2020 American College of Rheumatology Treatment Guideline

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Objective. The objective of this study was to understand patient perspectives to inform the voting process for the 2020 American College of Rheumatology (ACR) gout treatment guideline.

Methods. We conducted a panel meeting of eight patients with gout in Birmingham, Alabama. Patients were referred to the project by private and academic rheumatologists in the Birmingham area. All participants received orientation related to the guideline development process and evidence rating at the beginning of the meeting. With the help of a physician moderator, the patient panel reviewed nine key clinical scenarios and the supporting evidence and discussed their views and perspectives related to each. They also provided their preference for one of the two treatment options for each clinical scenario.

Results. The patient panel included eight men with gout. Of these eight participants, seven received their gout care from a rheumatologist and one from a primary care physician. Patients favored more active urate-lowering therapy (ULT) management and interventional management of gout flares to achieve desired clinical outcomes, resulting in unanimous consensus on choices related to six clinical scenarios: ULT initiation in gout, treat-to-target management strategy, use of pegloticase for refractory gout, starting ULT during a gout flare, using injectable treatments (over oral) for acute gout flares, and use of febuxostat in people with cardiovascular disease.

Conclusion. Knowledge of patient preferences and values is valuable and was influential for the development of the 2020 ACR gout treatment guideline.

INTRODUCTION

Gout is the most common inflammatory arthritis worldwide. Despite being called the "curable disease" (1), practice gaps in gout management continue to persist (2). Several rheumatology organizations have published gout treatment guidelines (3,4). The American College of Rheumatology (ACR) has published its 2020 update to the gout treatment guideline, reinforcing treat-to-target paradigms that should improve the quality of gout care (5).

There is widespread agreement from several leading organizations, including the National Academy of Medicine (formerly the Institute of Medicine), the Guidelines International Network (GIN), and the Appraisal of Guidelines for Research and Evaluation in Europe (AGREE), that patients should be involved in the development of clinical practice guidelines (6–8). Specific contributions

This study was supported by funding and resources of the American College of Rheumatology (ACR). The format and the design of this project was based on previous ACR patient panel meetings. The funding body did not play any role in in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

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SIGNIFICANCE & INNOVATIONS

- A patient panel consisting of eight patients with gout provided patient preferences and values related to gout and gout treatments to inform recommendation statements for the 2020 American College of Rheumatology gout treatment guideline.
- The patient panel favored more active management, preferring a treat-to-target management strategy (despite increased laboratory testing or provider visits), pegloticase for patients with severe manifestations of gout, and joint injections over oral medications for gout flares.
- The patient panel favored earlier urate-lowering therapy (ULT) use both through initiation of ULT for patients with mild or earlier disease and through starting ULT during a gout flare.

from such panels include not only a better understanding of the patient perspectives toward treatment and management decisions in the real-world scenarios but also an in-depth knowledge of their values and preferences (9) that likely play a critical role in treatment decision-making and adherence. Therefore, the ACR has prioritized and conducted patient panel meetings before the guideline voting panel meetings for several guidelines to inform these discussions (10,11).

As an example, in the 2015 ACR rheumatoid arthritis (RA) treatment guideline, the RA patient panel voiced stronger preference for triple therapy over monotherapy than did the provider panel (10). For the ACR guideline for perioperative management of rheumatic disease patients undergoing total joint replacement (25), the patient panel weighted concern for infection risk over flare risk. Per the authors of the joint replacement guideline, this "drove the direction of the recommendations (uniformly in favor of withholding any medications in which evidence from nonoperative populations suggested an increase in infection) (11)."

For the 2020 ACR gout guideline, in addition to patient representation on the 2020 gout guideline voting panel, we too conducted an in-depth focus group of patients with gout prior to the face-to-face meeting to understand patient values and preferences related to gout, gout management, and risk-benefit trade-off. The 2020 guideline supplemented their systematic literature reviews with input from patients on their values and preferences regarding the benefits and risks of treatment options. The objective of this focus group was to obtain the patient perspective (13–24) on various treatment aspects of gout being considered by the 2020 ACR gout treatment guideline voting panel prior to the panel's final vote (5).

PATIENTS AND METHODS

The patients with gout who composed the patient panel were identified from the local community via emails to ACR member rheumatologists in academic and private practice in the Birmingham area. A detailed description of both the study and patient participant expectations was provided to these rheumatologists, who shared it with patients they thought would actively participate. Interested patients reached out to the ACR directly with a brief statement of interest and an attestation from their rheumatologist that they had been diagnosed with gout. Invitation emails asking patients to participate in a 6-hour focus group were sent to patients by ACR staff. ACR staff also provided patients with the same gout guideline evidence report that was provided to the 2020 ACR gout treatment guideline voting panel. The Institutional Review Board at the University of Alabama at Birmingham approved this study.

The guideline leadership team selected several treatment scenarios to be shared with the patient panel, rather than the full set of questions and the full report, knowing that a limited amount of time was available for review and discussion. Scenarios focused on clinical questions (patient, intervention, comparison, outcomes [PICO]) in which patient preference was most directly relevant, including treatment choices for gout both for flares and long-term lowering of urate levels), treatment escalation when first-line treatment fails, treat to target, and the role of lifestyle modification. Some clinical scenarios that were less relevant to patient preference, such as checking the urinary uric acid level prior to prescribing a uricosuric medication for lowering the urate level, were excluded. A lay language version of the document was created and provided to patients for their review during the patient meeting discussions (Supplementary Appendix 1).

The lay language summary included the creation/simplification of two choice options for each PICO between A and B, a relevant literature summary synopsis, simple uniform coding for costs with dollar signs ($, $$, $$$), and a simplified system to summarize the risks and benefits of option A versus option B (! to !!!!; in cases of very low evidence, no sign). Mild, moderate, and severe gout were defined at the beginning of the discussion as follows:

1. Mild: no gout flares in the last year, one occasional flare in the last 5 years, serum urate level controlled, and quality of life (QOL) and functional ability with mild or no impairment
2. Moderate: one gout flare in the last year, serum urate level elevated, and QOL and functional ability with moderate impairment
3. Severe: two or more gout flares in the last year, serum urate level very high, multiple visible tophi, and QOL and functional ability severely impaired

The patient panel group session was led by an experienced moderator (JAS) (15,25) and lasted 6 hours. The session started with brief introductions of all participants, who were seated in a conference room with a U-shaped seating arrangement. Participants were provided with breakfast and lunch. The moderator reviewed the ACR evidence-based guideline development process, including the purpose of guideline development, the development and

interpretation of the evidence synthesis, the quality of evidence rating using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology, and the purpose of the patient panel meeting. The moderator asked the participants if they had any questions and addressed each participant question regarding various aspects of the introduction. Each participant then provided a brief account of their journey with gout.

Following this, the panel moderator reviewed the chosen clinical scenarios and the supporting evidence with the patient panel. Patient panel participants discussed their perspectives regarding the choices and what factored into their choices and why. This discussion occurred openly within the group; the moderator ensured that all voices were heard during the discussion by prompting participants who were less vocal during some discussions. The patient panel reviewed several clinical treatment scenarios for gout management, along with the evidence report, one at a time. For each scenario, participants voted for the main question by a show of hands or individual response in a round-robin fashion. We considered consensus to have been reached using the same 70% threshold used by the voting panel for the ACR 2020 gout treatment guideline (5). The discussion was recorded, transcribed verbatim, and reviewed for the accuracy of notes taken during the meeting by ACR staff.

This patient panel project was facilitated by the same ACR staff who facilitated the 2020 ACR gout treatment guideline development project, which took place approximately 2 weeks after the patient panel meeting, as well as by a rheumatologist gout guideline voting panel member (JAS). The ACR staff and panel moderator had expertise in guideline development and GRADE methodology.

RESULTS

Patient panel participants consisted of eight men (four who were White and four who were African American). Of these eight participants, seven saw a rheumatologist for their gout care and one saw a primary care physician. For each question, we first provide the conclusion from the panel followed by main discussion points, noting key exceptions or disagreements with the majority opinion.

Starting urate-lowering therapy for gout: When is it appropriate for a typical patient with gout to start urate-lowering therapy? Does it matter if gout is mild, moderate, or severe? The patient panel achieved unanimous consensus on urate-lowering therapy (ULT) initiation, with 8 of 8 people voting for it. The panel remained unanimous in their support of ULT treatment even for patients with mild gout because the panel members valued preventing long-term negative outcomes, such as recurrent flares or tophi, over any inconvenience of daily ULT. This was based on their shared experience that during a gout flare, they would do anything to make pain go away (or prevent it from happening). Interestingly, many of the patients on the panel reported that they were initially hesitant to start ULT, but after experiencing improved control of inflammatory symptoms and reduction in tophi (in some participants), they became strong advocates for early intervention focused on lowering urate levels (Table 1). They acknowledged that patients with gout who experience only infrequent flares in the beginning may be less willing to take long-term medication. A patient said, "Mine is mild, but by taking my medication every day; that's what keeps it mild." The patient panel acknowledged that the goal of ULT for gout is to eliminate flares and/or tophi to improve overall QOL, which is achieved with ULT (Table 1).

Anti-inflammatory prophylaxis when starting or titrating ULT: Is it preferable to take prophylaxis medicine or not for the first 3 to 6 months? Does it matter if it is 3 or 6 months? Although the majority (six of eight patients) valued anti-inflammatory prophylaxis with ULT initiation with consensus (75% endorsement; consensus was defined as 70% or more endorsement), the patient panel did not achieve unanimous agreement.

Most patients were in favor of taking anti-inflammatory prophylaxis when starting ULT. Most patients were comfortable with taking colchicine or taking nonsteroidal anti-inflammatory drugs (NSAIDs) (Table 1). Although some patients had experienced side effects with either NSAIDs or colchicine, they thought that taking the alternative drug was reasonable to prevent flares during ULT initiation (Table 1).

One patient with concomitant kidney disease would not take it because he worried about potential kidney side effects. If there were a safer alternative that would not affect the kidneys, he would take it.

The duration of anti-inflammatory prophylaxis (3 versus 6 months) was discussed. Whereas some panel members were comfortable with a 6-month duration of prophylaxis, others questioned the value beyond 3 months, and wanted to see the evidence of use for 3- versus 6-months.

Slow uptitration of ULT: Is it preferable to start ULT at a low dose and slowly increase the dose or to take a fixed higher ULT dose? Although the majority (six of eight patients) valued slow uptitration of ULT, the patient panel achieved consensus (75% endorsement) but did not achieve unanimous agreement.

Two members favored a fixed ULT dose regimen based on their experiences because a fixed dose achieved desired results without adverse events, and a reduction of the ULT dose led to frequent gout flares in one patient. The inconvenience of frequent laboratory testing for titration was discussed; most patients understood the reason and were comfortable with it (Table 1).

For the two patients supporting fixed-dose initiation, both had started allopurinol at 300 mg daily, with good results and

Table 1. Representative patient quotes related to specific gout scenarios and clinical situations, with themes listed under each clinical scenario

Themes/subthemes	Representative patient quotes
Clinical scenario 1: Starting ULT for gout	
Mild symptoms at first	"I was just treating symptoms and I thought I was fine."
	"Mine kind of started that way, mild. I was ok with it at first. I didn't want daily medication."
	"I never heard of tophi."
	"Mild is not the worry; several of us are mild now. Mine is mild, but by taking my medication every day; that's what keeps it mild."
Control of gout with ULT	"I have mild also, but I believe in keeping my pill on."
	"I do it [take ULT] to reduce the risk of gout flare and the tophi."
	"I think allopurinol is one of the best medicines you can take."
	"It's a pill you take once a day. I have not had a gout flare since I started it."
	"Allopurinol is affordable for most people."
Fear of tophi and embarrassment	"I always wore long sleeves shirt, it [deformity due to tophi] was very embarrassing. My range of motion was not normal."
	"I had grandma with swollen knuckles because of her gout- I don't want those tophi."
	"I do have that tophi in my elbow now that you are talk about it, I never knew what it was."
Other concerns: Side effects, inconvenience	"Side effects was a concern for me, it wasn't to the point of stopping me from taking medications for my gout. It's always at the back of my mind."
	"Taking any pill every day is a pain in the butt."
	"I was willing to go through mild symptoms and still avoid taking medications."
Ability to control moderate/severe gout	"No question, I would take the mediation."
	"You are going to do everything to not get it this bad."
	"I had my symptoms. The gout was worse than my surgery."
	"When you have gout in heels, every step makes you hurt."
	"I have a sports car. I have to push the clutch with my cane when I have gout."
	"I couldn't go to events. I was on crutches, I would do nothing."
	"When I had rotator cuff surgery, they completely opened me up. Then, I had a gout attack in my elbow and wrist on the same side. They put me in a sling. I was in the worst pain in my life."
	"When I get the attack, just hit me with a shot- it's so bad."
Clinical scenario 2: Anti-inflammatory prophylaxis with ULT initiations	
Easy availability and prior experience	"I would do it every day. It's [ibuprofen] over the counter, I would walk down to the convenient store."
	"You are talking about Aleve. Most of us know side effects of Aleve, so we are comfortable with it. Why wouldn't you take it, if it is going to prevent gout flares?"
Side effects	"Everything makes me sleepy. If I take Aleve I am groggy. I can't take that stuff in particular. But the other pill, I may take."
	"There are trade-offs with everything in life."
	"Age plays a factor. When I was younger, I could take any medication."
Cost considerations	"If you are paycheck to paycheck, you are in a different position. I would sometimes take it."
Clinical scenario 2: Duration of anti-inflammatory prophylaxis: 3 vs. 6 months	
Personal experience	"If I can tolerate it for 3-months, maybe I can continue to take it."
Duration matters	"It doesn't matter if the duration is 3- vs. 6-months."
	"I would question whether I have to take it 3 months or 6 months."
Clinical scenario 3: Start ULT low, go slow rather than start ULT at a fixed dose	
Personalized approach	"Opportunity to see if the flares are bad. Then go slow to help them."
	"Blood test after blood test, then I got to a stable level. And now I am at 300 mg dose."
	"Draw up your personal plan, [t]hen have your uric acid checked, [a]nd then change [t]he dose; [t]his is clearly more definitive."
More conservative	"Always want the [l]owest dose, [t]he only negative is more doctor visits, [o]r more [b]lood draws. Is it that inconvenient?"
	"It's like checking the battery in the alternator and not taking out the engine first."
Avoid reducing ULT dose too quickly	"I've always been a fixed dose; I never have to go back to the doctor."
	"Gout is gout- it shouldn't be that hard."
	"I started at 300 mg dose and I don't want to drop it to 100 mg. Because 300 mg works just fine with no side effects, no need to keep cutting it back."
	"My primary care dropped me from 300 mg to 100 mg allopurinol. Then my uric acid started going up. Then my rheumatologist moved me back to 300 mg so I ended up with 300 milligrams was always ok."

(Continued)

Table 1. (*Cont'd*)

Themes/subthemes	Representative patient quotes
Clinical scenario 4: Starting ULT during a flare	
Window of opportunity	"Capture it when the attention is there."
Rapidity of benefit	"When I'm in pain during the flare. It's better to have something in your body when you are in a flare." "My gout - this was discovered when I was in the hospital for different reason. They started it right away." "If you are concerned about your health, you want to take it."
Easy access to ULT	"If you prescribe me allopurinol during the flare, then I have the medication. I don't have to call the doctor's office or remember to ask."
Clinical scenario 5: Treating to target with active management strategy	
Prevention of flares	"It's worth it not to have flares in the long run."
Patient preference	"I support the active approach. I went every three months. She would do labs, [i]t wasn't that inconvenient, would mess up my lunch hour, but it was worth it." "I always ask what my uric acid is."
Understanding the disease causation	"Some things seem obvious – for example, having continual high blood pressure would seem to mean a person would have a higher likelihood of having a heart attack. It is the same with uric acid level and flares. Patients have lived this, they said, so they have experience that when their levels are high, flares increase in intensity and frequency."
Time and cost	"The only drawback I see is the need for more labs and doctor visits. It would cost me $40 every time. If you didn't have insurance, maybe it costs a lot more."
Clinical scenario 6: For a patient on febuxostat who had cardiovascular disease, should they stop or change the drug?	
Benefit/risk balance	"If it's helping your quality of life, and it hasn't caused a heart problem, why change it."
Issues with alternatives	"If you're working it might be challenging to take pegloticase infusions."
Cost	"If not financially crippling, then yes."
Clinical scenario 7: Pegloticase in ULT failure with frequent gout flares, tophi, or uncontrolled serum urate levels	
Efficacy	"This is the best thing out there. It really worked for me, when nothing else worked." "This is worth it. The nurse is standing there by you all the time."
Cost	"The obvious key is money."
Clinical scenario 8: Managing gout flares: Oral, systemic injection, joint injection	
Efficacy/rapidity of improvement	"I don't like the needle. I went in a wheelchair to my rheumatologist. I said give me a shot of the joint. As soon as he did that, no more wheelchair." "I would rather have a shot in the joint, rather than my butt. It always works better when they inject my joint." "After the shot of the medicine in my joint, I went from a wheelchair to crutches in not much time." "I was limping and they gave me a shot in the muscle, And it felt a lot better." "I walked in limping. Within one hour of getting colchicine, I felt better and it all resolved in three days."
Clinical scenario 9: Lifestyle modifications: Diet change	
Efficacy	"Absolutely. I have to start eating the house. When do you live without family and have frequent attacks, [y]ou've got to do what you've got to do." "If it triggers your gout."
Clinical scenario 9: Lifestyle modifications: Weight Loss	
Other effective strategies	"Depends a lot on whether you're being under control with other means." "It's huge."
Lack of prioritization/need	"Not really, I got it well controlled." "I don't think doctors talk to you about weight problem with gout. Maybe they should?"
Clinical scenario 9: Lifestyle modifications: Alcohol use	
Extent of alcohol use issue	"It also depends on how much you are eating or drinking."

Abbreviation: ULT, urate-lowering therapy.

no adverse events. A report by one patient of gout exacerbation after an allopurinol dose reduction was greeted with marked disapproval by the rest of the panel for this strategy.

Starting ULT during a gout flare: Would you rather start ULT during a gout flare or wait until the flare was over?

The patient panel achieved unanimous consensus on starting ULT during a flare rather than waiting until after the gout flare resolution.

Patients valued receiving a ULT prescription at their visit for a gout flare so that ULT could be started right away.

The panel was in favor of starting ULT during a gout flare. They considered this convenient because the patient is already seeing the doctor (Table 1). The panel indicated that there is less likelihood of the patient starting ULT later, after they have left the doctor's office or the hospital, and it is beneficial to be on ULT long-term. They acknowledged the potential negative impact on the current flare but still supported this approach. Two patients had been diagnosed with gout while in the hospital and were both given a prescription of allopurinol before hospital discharge, which worked well for them because they had no new gout flares and no perceived prolongation of the current gout flare.

The patient panel also was not concerned about receiving information about management of the gout flare and long-term management of their gout at the same time. The patient panel had a strong preference to start ULT "as soon as possible" and saw the flare as a good window of opportunity to focus patient attention and motivation to start ULT. The members understood the hypothetical concern about overloading patients with ULT information and medications during a gout flare, but the panel felt that most patients would be able to adequately follow ULT education during a gout flare (Table 1).

Treat to target with ULT: Would you prefer to receive the more active management strategy or a fixed-dose strategy? The patient panel achieved consensus on treat to target with the more active management strategy, with all eight patients agreeing with this approach.

Patients preferred a personalized approach in the active management strategy, in which doctor visits and laboratory testing allowed for the selection of the most optimal ULT dose for their disease (Table 1):

> It's worth it not to have flares in the long run.
> I support the active approach. I went every three months. [My doctor] would do labs, [i]t wasn't that inconvenient, would mess up my lunch hour, but it was worth it.
> I always ask what my uric acid is; I want to know.

Use of febuxostat in a patient with a history of cardiovascular disease: Would you stop or change the drug? For patients on febuxostat and clinically doing well, all eight patients agreed that continuing febuxostat would be preferable over stopping or changing ULT, regardless of their cardiovascular risk, so long as the patient had not experienced a cardiovascular event. However, if an effective alternative with fewer side effects existed, they agreed with changing to that alternative. They considered this decision to be very specific to a patient's situation (Table 1).

Use of pegloticase for tophi and gout flare reduction when other ULTs have failed to control gout: Would you begin pegloticase? Would the severity of gout flares or tophi influence your choice? The patient panel achieved unanimous agreement to begin pegloticase for patients with severe or very severe gout manifested by frequent flares and tophaceous gout. The patient panel focused on the impact of pegloticase on tophi and gout flare reduction and overall QOL. For patients with moderate severity of flares and tophi that negatively impacted QOL, the panel still recommended beginning pegloticase. The panel did not discuss mild gout in this clinical situation.

Because only one of the patient panel members had used pegloticase for his gout, he shared his experience with the group, both of tophaceous gout with significant disability and of a favorable response to pegloticase (significant improvement in his QOL and reduction of flares) when all else had failed: "This is the best thing out there. It really worked for me, when nothing else worked" (Table 1). Patients agreed that with active disease (ie, frequent flares, tophi) for which other ULTs had not worked, if the patient can afford co-payments for it and their insurance covers it, then the patient would do it: "The obvious key is money." Patients downplayed the risk of an infusion reaction or allergic reaction because they considered this rare and that it usually happens when the patient is still in the medical facility. The patient panel made no distinction between severe or very severe gout for making this treatment decision.

Managing gout flares: Given risks and benefits, do you have a strong preference for one delivery route over another? Does this matter, depending on the severity of the flare? The patient panel achieved consensus on preferring injectable over oral medications for gout flares because of rapidity of relief and preferred joint rather than intramuscular glucocorticoid injection; all eight patients agreed. The panel was also in agreement about using oral medications at home to prevent and abort gout flares early as well as using intramuscular injections for more severe flares (no vote for this statement).

The patients recognized that those with concomitant conditions, such as diabetes or kidney problems, or those who are hospitalized and worried about increased infection or gastrointestinal risks would prefer joint injections as a first option, but having quick access to joint injections that are given by well-trained professionals (such as rheumatologists) is very important and sometimes lacking (Table 1):

> I don't like the needle. I went in a wheelchair to my rheumatologist. I said give me a shot of the joint. As soon as he did that, no more wheelchair.
> I would rather have a shot in the joint, rather than my butt. It always works better when they inject my joint.

Lifestyle changes: How willing are you to change your diet, change your intake of high-purine foods and of drinks with high-fructose corn syrup, change your alcohol use, and consider weight loss to prevent future gout flares? The patient panel achieved consensus on making dietary changes but only as an adjunct to medication therapy and only if gout cannot be controlled any other way; six of eight people agreed (75% endorsement). Reduction in alcohol use and weight loss were considerations for the patient but only if discussed by their provider as effective strategies for gout management (no vote for this statement).

Patients discussed this issue with great interest. They agreed that if they had moderate or severe gout, they would make dietary changes only if gout cannot be controlled any other way and if that would help prevent gout flares (Table 1). However, if they had mild gout that was controlled by medication, then a diet change was not a priority. Most participants either did not drink alcohol or were not regular drinkers. However, some had curtailed their occasional beer drinking because of the risk of gout flares. Many people continued to consume drinks with high-fructose corn syrup, such as sodas. The panel considered weight loss to be very important in general as well as, perhaps, for improving gout control. However, they realized from personal experience the difficulty in achieving and sustaining weight loss and the possibility that some weight loss diets increase the risk of gout flares.

Risk-benefit considerations for starting drugs for gout treatment, including ULT. Patients discussed several scenarios and considered risks (adverse events; patients commonly used the term "side effects") and benefits of starting a particular drug (to reduce flares) to treat their gout. We asked them the following question: For what amount of benefit (50% or 90% gout flare or tophi reduction, 50% or 90% improvement in QOL, or 50% or 90% chance of achieving the target serum urate level) will patients accept [X] amount of risk (from 1% to 100%)?

The patient panel agreed that to effectively treat a severe gout flare they would accept a higher risk of side effects.

In general, patients were willing to tolerate some non-severe serious adverse events (SAEs) to benefit from gout treatments (Table 2). Patients were willing to accept more risk for the treatment of tophi. For a 50% or a 90% gout flare reduction or improvement in QOL in moderate-severe gout, people considered a low-medium risk of SAEs to be acceptable (Table 2). For a 50% or a 90% higher chance of achieving a target serum urate level, patients would accept low-medium risk of SAEs (Table 2).

DISCUSSION

Following the ACR guideline methodology to directly involve patients in guideline development, in this qualitative study, a patient panel consisting of patients with varying severity of gout discussed key clinical scenarios related to the management of gout. The severity of pain from gout flares and functional limitations and/or disfiguring appearance of tophi drove this patient panel's passionate desire to avoid gout flares and reduce tophi as effectively as possible. This resulted in recommendations that valued more active management over less aggressive options and included recommendations to start ULT for patients with early disease and to use a more active treat-to-target protocol (despite additional laboratory testing or provider visits) to achieve better control of their gout.

Table 2. Overall summary to the benefit/risk by the patient panel

	Non-SAEs (eg, nausea, itching, diarrhea)	SAEs (eg, myocardial infarction, cardiovascular events, etc)
Flare reduction		
50%	15%-40%	0%-<5%
90%	15%-50%	<1% (mild gout); up to 5%, moderate-severe gout
sUA level reduction		
50% chance of achieving target sUA level	20%-50%	1%-10%
90% chance of achieving target sUA level	25%-50%	1%-20%
Tophi reduction		
50%	50%	0%-40%
90%	50%-90%	5%-80%
QOL improvement		
50%	10%-100%	4%-10%
90%	50%-100%	2%-70%

Note. SAE was defined per the US Food and Drug Administration definition as an event that results in hospitalization, permanent injury, or death and includes (but is not limited to) conditions such as myocardial infarction, cardiovascular events, gastrointestinal bleeding, kidney failure, infection requiring intravenous antibiotics, and hospitalization for up to 2 wk. Patients referred to "adverse events" as "side effects." We asked the following question to each member of the patient panel one at a time for each domain and each threshold: For what amount of benefit (50% or 90% gout flare or tophi reduction, 50% or 90% improvement in QOL, or 50% or 90% chance of achieving the target sUA level) will patients accept [X] amount of risk (from 1% to 100%)? Abbreviations: QOL, quality of life; SAE, serious adverse event; sUA, serum urate.

Starting ULT during a gout flare, after considering all benefits and risks and their overall balance, was the influential consensus feedback from the patient panel for the 2020 ACR gout guideline voting panel. The patient panel considered the current gout flare as a "good window of opportunity" to start ULT to enhance patient attention and motivation and potentially improve long-term adherence and persistence with ULT. This approach was considered practical and feasible because it would allow the patient to start ULT as soon as possible, and the patient panel did not consider education about gout flare management alongside information on ULT therapy to be too much information at once.

The patient panel achieved consensus on early ULT initiation to avoid flares, reduce functional limitation, improve QOL, and avoid longer-term negative outcomes, such as tophi, regardless of disease severity (even in mild gout). The patient panel also achieved consensus on treat to target with a more active management strategy than a fixed strategy. The panel also endorsed the use of pegloticase for patients with severe gout, including tophaceous gout.

These were important discussions that can inform health care providers regarding patient goals and preferences for gout treatment in clinic settings. We believe that in-depth qualitative work such as this, done prior to the development of a treatment guideline, is essential to understand and incorporate patient priorities, preferences, and values into a treatment guideline. Specifically, these discussions were important to the development of the 2020 ACR gout treatment guideline (5). In the absence of such work, there is a risk of formulating potentially meaningless recommendations for ULT use and/or recommendations that are paternalistic and that may not account for factors that may be weighed differently between patients and health care providers.

The patient panel discussion summary related to several specific questions was also useful because it was reviewed with the 2020 ACR gout guideline voting panel members prior to their discussions and final vote on these same clinical scenarios (see Supplementary Appendix 1). In addition to comments on specific recommendations, the patient panel feedback on the importance of laboratory and clinical outcomes helped affirm the voting panel's consideration of the serum urate level as being among the critical outcomes as important as flares and tophi.

On average, patients valued an SAE "much more" and a non-SAE "more" than a benefit, such as reduction of flares, achievement of the target serum urate level, resolution of tophi, or improvement in QOL. This highlights that risk averseness of patients related to medication use is similar to that demonstrated for other chronic conditions and long-term medications and in other guideline patient panels (10,12).

Our study results should be interpreted while considering study limitations. The purpose of the patient panel was to provide patient input into the guideline development, which was effectively accomplished. However, because of time constraints, we were unable to assess all the clinical scenarios that were voted on by the gout guideline voting panel. Optimal management in routine clinical care should use shared decision-making based on individual patient values, preferences, and clinical status.

Because this was a single-center study with only eight patients, the generalizability of these findings beyond the scope of the original intent are limited. Although we selected patient panel members with diversity across disease severity, age, race/ethnicity, and health care receipt from private versus academic rheumatology offices, they are not representative of all patients with gout. Despite invitations being extended, no women with gout attended the panel meeting. Because patients were nominated by their physicians, their attitudes and views might be more provider concordant. Because of limited time for the patient panel meeting, we were unable to perform a discrete choice experiment for trade-offs between efficacy and adverse events, which would have provided us with more valid estimates of preference.

In conclusion, a patient panel consisting of people with varying degrees of gout severity provided exceptional insights into several clinical scenarios that are common but for which management is frequently debated between primary care physicians and rheumatologists. In the absence of high- or moderate-quality evidence, or when there is a balance between benefits and risks, patient values and preferences become very important in making shared treatment decisions.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual contact, and all authors approved the final version to be published. Dr. Singh 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.

Study conception and design. Singh.
Acquisition of data. Singh, Neogi, FitzGerald.
Analysis and interpretation of data. Singh.

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