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Original article

Disease modification in gout: a qualitative study of gout expert rheumatologists

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Abstract

Objective. The aim was to examine the views of health-care providers regarding disease modification in gout, with the potential to derive a provisional set of domains for disease modification in gout.

Methods. A qualitative nominal group study was performed with 20 gout experts (15 expert/expert panel members of the 2012 and/or 2020 ACR gout guidelines and/or 2015 ACR/EULAR gout classification criteria) about what constitutes disease modification in gout: 'What sorts of things do you think constitute a change in the course of disease in gout? (positive); what are all the ways in which gout as a disease can be modified?'

Results. Decrease in gout flares was rated number one rank in all six nominal groups as indicative of disease modification in gout, followed by serum urate lowering, which was rated number one rank in one of the six nominal groups (tied score with flares in one nominal group). Other components of gout disease modification were to improve quality of life/productivity; restore function; reduce/eliminate pain; reduce tophi burden; and joint preservation or resolution of joint damage. Potential additional components that were not ranked in the top three votes within each nominal group were: decreasing health-care cost/utilization; reducing cardiovascular/renal morbidity/mortality; and stopping formation of urate crystals.

Conclusion. This qualitative study provides a provisional set of domains for disease modification in gout. Future studies for the development of thresholds for disease modification domains and wider consensus on this definition are needed.

Key words: gout, qualitative study, crystal arthropathies, outcomes, rheumatologist, provisional definition, disease modification

CLINICAL SCIENCE

Key messages

- Clinicians' views of disease modification in gout were examined in nominal groups.
- Gout flares, serum urate, quality of life, function, pain, tophi and joint preservation were proposed.
- A wider consensus on gout disease modification domains and definition of thresholds is needed.

Introduction

Gout management focuses on treatment and prevention of acute flares, chronic synovitis, tophi and joint destruction, using anti-inflammatory drugs and urate-lowering therapies (ULTs) [1]. Provisional gout remission criteria were developed that included serum urate, flares, tophi, pain and patient global assessment [2]. They were validated against the urate burden on dual energy CT imaging [3]. Although disease remission is a highly desirable treatment goal, only few achieve remission [3]. Therefore, gout disease control remains an important treatment goal for most people who cannot achieve remission.

Patients with gout ranked the treatment of gout symptoms and serum urate [SU] lowering as the best long-term strategy [4]. Patients ranked prevention and better

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management of gout flares, improvement in function and remission of disease symptoms as the patient-preferred goals for gout management [5]. The regulatory agencies accept serum urate lowering for the approval of ULTs [6, 7], as a potential surrogate disease outcome.

Disease modification is a well-known concept for inflammatory arthritis conditions that present like gout, including RA [8, 9]. To my knowledge, no consensus exists on the definition for disease modification in gout. Therefore, the study objective was to examine views and opinions of the leading gout experts on disease modification in gout.

Methods

Study sample

Rheumatologists (also referred to as doctor or medicine [MD] or physician) who were authors/expert panel members of the 2012 and/or 2020 ACR gout guidelines and/or 2015 ACR/EULAR gout classification criteria or with published peer-reviewed gout articles were invited to participate. There was no compensation for participation. Given that this discussion focused on the opinions of physicians with no inclusion of patients, no institutional review board approval was needed.

Nominal group technique sessions and analyses

The study principal investigator (J.A.S.) drafted the study question: 'What sorts of things do you think constitute a change in the course of disease in gout? (positive)'; what are all the ways in which gout as a disease can be modified?. The nominal group technique (NGT) is a qualitative research method like a focus group that taps the experiences, skills, views and opinions of the participants and is widely used [10–16]. The NGT is well suited for an in-depth examination of a question.

An experienced moderator (J.A.S.) led the NGT sessions [5, 17]. A modified NGT conducted virtually using health insurance portability and accountability act (HIPAA)-compliant Zoom was used instead of an in-person session, because participants were in the USA, Europe and Australasia, and owing to the coronavirus disease 2019 pandemic [18]. The virtual platform for NGT has been used successfully instead of in person [19, 20]. We adapted our on-line Zoom NGT sessions using the same modifications as previously. The study principal investigator used his personal contact list and/or published email addresses to invite all experts via email invitation that described the NGT and its purpose. Those who provided their availability in response to the initial email were invited to participate.

The study principal investigator/moderator presented a brief (5 min) PowerPoint presentation to the nominal group, highlighting examples of disease modification (Supplementary Data S1, available at *Rheumatology* online). The nominal group question was shown to the group, and the moderator asked whether the question was clear or not. The following clarifications were offered for the NGT question: 'What sorts of things do you think about when you are thinking of modifying gout as a disease? What are all the ways in which gout as a disease can be modified? We are trying to understand as to what constitutes disease modification in gout.' Each NGT session lasted 1 h.

After viewing the question, each participant independently generated as many responses as possible using short phrases or brief sentences on paper. The NGT moderator collected the response of each participant in a round-robin fashion, one at a time, and recorded it verbatim on a PowerPoint slide visible to each participant, until all responses were collected. Thereafter, the participants discussed and elaborated on each response. They combined responses, when appropriate. Once all responses were discussed, each participant independently voted for the top three responses. Two key modifications made to the in-person NGT process were similar to that previously described [19]: a whiteboard/PowerPoint functionality was used to replaced a flip chart, and the private chat feature of Zoom was used for the collection of anonymous voting and ranking of ideas instead of individual index cards.

The moderator created a rank order for responses within each nominal group based on the total score for each statement/theme, with the highest score corresponding to the top rank.

Each NGT session was audio-recorded and transcribed verbatim (D.F.). Transcriptions were examined to confirm the accuracy of all nominated responses, to review discussions and to ensure saturation, as groups were completed. I compared the number of NGT sessions where each statement was in the top three ranks, the number of NGT sessions in which it received any vote, and the total percentage votes for each statement/theme.

Ethics/institutional review board approval and consent to participate

No patients were involved in this discussion forum; therefore, no institutional review board approval was needed. All participants volunteered to participate in the nominal groups and gave permission at the beginning of the conversation for audio- and videorecording of the conversations.

Consent for publication

No individual person's data were presented in any form in this study; therefore, no consent to publish is required.

Results

Study participant characteristics

Six nominal groups with 20 gout-expert rheumatologists were conducted. Of these, 15 (75%) were from the USA, 3 from Australasia and 1 from Europe. Eight were women (40%). Fifteen (75%) were authors/expert panel members of the 2012 and/or 2020 ACR gout treatment

Table 1 Priority ranking of the top components of disease modification in gout by each nominal group

Priority ranking	Total votes
Nominal group 6 ($n = 3$): three female	
A. Reducing the number of gout flares/ultimately having no more flare would be goal/decreased number of gout flares/no need for prednisone, NSAIDs or colchicine over the last 12 months for gout treatment. ULT alone controls all symptoms of disease/along with absent flares	9
B. Reducing serum urate/serum uric acid at target (<6 mg/dl)/target uric acid of solubility	5
C. Improved quality of life: pain reduction, a gout-specific patient acceptable state	2
D. Pain reduction	1
E. Reducing tophi volume/number of tophi/reduction or elimination of tophi	1
Nominal group 5 ($n = 2$): two male	
A. Flare resolution/symptom burden/pain level/decreased morning stiffness/chronic pain/recurrent acute pain	5
F. Joint preservation/on imaging: erosion/bone remodelling/resolution of double contour signs/snowstorm appearance	4
G. Improved function/joint function	2
C. Improved quality of life	1
Nominal group 4 ($n = 4$): one female, three male	
A. Turn off gout flare/prevent gout flare/reduction in the number of flares/relieve pain/end pain/fewer flares, less pain, less time lost from work/less interference of gout flares in hobbies and non-work activity/clinical flares	11
B. Serum urate (SUA) has trended down as well	4
C. Increased productivity/reduce number of days lost at work/restore full quality of life/improvement in scores in depression indices/improvement in quality of life and depression/overall improvement in measure of quality of life/prevent loss of workday/prevent loss of employment	3
F. Prevent radiographic damage/arrest progression of radiographic damage/long-term joint damage if any halted since the patient is not on optimal ULT/stopping of reversal of joint damage/structural joint damage	2
H. Reduced cost in terms of medications needed for acute flares/avoid any hospitalization long term/eliminate the need for urgent care/emergency department visit/reduce number of gout-related clinical care visits/prevent the need for inpatient medical care	2
E. Fewer of no tophi/prevent incident tophi/reduce the size of existing tophi	1
I. Eliminate elevated risk of mortality/eliminate heightened risk of cardiovascular disease/possibility for improvement in kidney function or slower deterioration/prevent incident chronic kidney disease/improved kidney function/possibly less coronary disease/improve blood pressure/reduce weight, reduce blood pressure, reduce hyperlipidaemia/decrease weight	1
Nominal group 3 ($n = 3$): three male	
B. Reduced serum uric acid/urate lowering	6
A. Reduction of gout flares/flare reduction/decrease flares in a given time	6
F. Reduction of radiographic destruction/skeletal structure stabilization/decreased structural bone changes	4
E. Reduction of tophi size that might inhibit joint functions/crystal dissolution/reduction of disfigurement owing to gout deposits/decreased tophi, if present, or tophi resolution	2
Nominal group 2 ($n = 3$): one female, two male	
A. Decrease in flare frequency and/or intensity: reduction in rate of flares; reduction in severity of flares; decreased frequency of acute attacks; reduction or stabilization of number of joints involved in flares	9
E. Decreased size in tophi (count, size)/resolve or shrink tophi/restoration of mobility/function owing to urate deposits/prevention of tophaceous infection (rare)	4
F. Prevent joint damage/no new erosions/blockage of bony erosion/healing of bony erosion/reduction in total mass of urate deposition on cartilage, soft tissue etc., meant to say, including tophi	4
D. Improvement in chronic pain associated with gout	1
Nominal group 1 ($n = 5$): three female, two male	
A. Change in inflammation: clinically this is evident via flares	12
E. Change in MSU crystal burden: s.c. tophus	6
F. MSU crystal deposition on US/dual energy CT etc.	3
F. Change in joint structural damage (erosion, joint space narrowing, new bone formation)	4
C. Changes in other patient-reported domains could be added, because these are important when considering changing the disease course: activity limitation/disability, pain, patient global assessment; (and productivity)	4
J. If we can stop (urate) crystals from forming	1

A: gout flare; B: serum urate; C: quality of life/productivity; D: pain; E: tophi; F: joint preservation/damage resolution, usually on imaging studies; G: function; H: cost/health-care utilization; I: cardiovascular/renal morbidity/mortality reduction; J: stop urate crystal formation. ULT: urate-lowering therapy.

guidelines, and three were co-authors on the 2015 ACR/EULAR gout classification criteria.

Nominal group rankings

The top nominated responses from each nominal group are listed in Table 1 (details, Supplementary Table S1, available at *Rheumatology* online). In the subsections below, responses nominated that received any votes in at least one nominal group are listed.

Reducing gout flares and associated symptom burden
All six nominal groups voted this in the top three ranked positions, and all six voted it to the top rank (Supplementary Table S2, available at *Rheumatology* online). It achieved 45% of all votes (52 of 114) across all nominal groups. Representative quotes from participants are: 'Gout flare is the measure of inflammatory disease. It's what the patient reports is important. That's how they say their allopurinol is working or not.' (nominal group #2 [NG2], doctor of medicine #1 [MD1]); 'It's what the patients feel. It's the metric for the underlying process.' (NG2, MD2); and 'Gout flares at the ULT initiation is one of the big problems, and the area where primary care struggles, when we think of the ULT as a disease-modification agent. That is where we can help our colleagues understand this dilemma.' (NG2, MD3).

Reducing or normalizing serum urate
Three nominal groups voted this to the top three ranked positions, and one group voted it to the top rank, where it tied in votes with gout flare reduction (Supplementary Table S2, available at *Rheumatology* online). It achieved 13% of all votes (15 of 114). Representative quotes from participants are: 'I see the treat to target as the means to goal to which we want to get. Patients value it. I see it as the mean and the method to get to what we really want. I see the push-back that we get it in the guideline. I am sensitized to this a little bit.' (NG2, MD2); 'Primary care view that flares are the problem. If urate deposition is intrinsically a problem, then it's much harder to argue that urate is divorced from urate crystals.' (NG2, MD1); and 'I think serum urate is the unifying element.' (NG1, MD2).

Quality of life/productivity
Two nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 9% of all votes (10 of 114). A representative quote from participants is: 'Gout affects some people's life much more than the others; severity is so variable.' (NG2, MD1).

Pain
None of the nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 2% of all votes (2 of 114). Representative quotes from participants include: 'Related to acute flares; but also, chronic pain from the disease.' (NG 6, MD1); and 'Quality of life—I think it's probably second for the patient, the first is pain.' (NG 4, MD2).

Tophi
Three nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 12% of all votes (14 of 114). Representative quotes from participants are: 'Sometimes, if it is visible, fingers or elbows, they think it's really ugly, and they are embarrassed and having that improve is a big deal for patients.' (NG6, MD2); 'Tophi are what cause joint destruction, plain and simple.' (NG3, MD3); and 'Preventing tophi is what you need before you shrink the tophi—usually with a less aggressive approach.' (NG2, MD1).

Joint preservation/damage resolution, usually on imaging studies
Four nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 18% of all votes (21 of 114). Representative quotes from participants include: 'I think it's the concept of short- *vs* long-term outcomes. Flares is now and immediate; long term is structural integrity.' (NG4, MD1); and 'Prevention or healing of gouty erosions is important. Directly correlates with the presence of urate crystals in the joints.' (NG3, MD1).

Function
One nominal group voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 2% of all votes (2 of 114). Representative quotes from participants include: 'Avoiding the loss of pleasurable diet and lifestyle habits.' (NG5, MD2); and 'Workday missed and the loss of employment.' (NG3, MD2).

Cost/health-care utilization
None of the nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 2% of all votes (2 of 114). Representative quotes from participants include: 'People utilize a lot of emergency room services due to gout, could that reflect whether the disease is getting better or worse?' (NG1, MD3); and 'Reducing pain meds, emergency department and medical visits, and hospital admissions; costs increased for medical care.' (NG5, MD2).

Cardiovascular/renal morbidity/mortality reduction
None of the nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 1% of all votes (1 of 114). Representative quotes from participants include: 'For me, the trouble I have is—sicker gout patients have co-morbidity and other issues. But if we fix their gout, would it fix these co-morbidities? I don't know if that will happen.' (NG1, MD3); and 'Reducing NSAIDs, prednisone should help co-morbidities.' (NG1, MD2).

Stop urate crystal formation

None of the nominal groups voted this to the top three ranked positions (Supplementary Table S2, available at *Rheumatology* online). It achieved 1% of all votes (1 of 114). A representative quote from participants was: 'It also misses things we don't know or understand as yet—how crystals form. If we can stop crystals from forming.' (NG 1, MD3).

Discussion

This qualitative study examined the concept of disease modification in gout with leading gout experts. The domains nominated for disease remission in gout were as follows: gout flares; serum urate; quality of life/productivity; function; pain; tophi; and joint preservation. Potential additional domains were health-care cost/utilization; cardiovascular/renal morbidity/mortality; and to stop urate crystal formation. Several findings in the study deserve further discussion.

This proposed list of gout disease modification components from this study is consistent with the OMERACT domains selected for gout trials: (1) acute gout studies: pain, inflammation, function, patient global and safety; and (2) chronic gout studies: serum urate, gout flare recurrence, tophus regression, joint damage imaging, health-related quality of life, musculoskeletal function, patient global assessment, participation, safety and tolerability [21, 22]. Most NGT participants had not previously participated in OMERACT domain selection study. The consistency between these different exercises supports the validity of findings in this qualitative study.

It is not surprising that the two highest ranked domains for gout remission were gout flares (46% of votes) and serum urate (13% of votes). Previous studies have highlighted their importance for gout management. Specifically, gout flares constitute a major burden in people with gout and are easy to measure with a validated patient-reported outcome measure [23, 24]. Serum urate is a well-accepted surrogate outcome measure, assessed with a standard bioassay that is sufficient for regulatory agency's assessment of efficacy of ULTs in gout [6, 7] and used commonly to monitor ULT effectiveness in clinical practice. In addition to these two highly voted domains, several other components are also identified.

The nominal groups also identified three patient-reported domains to be included in disease modification: quality of life/productivity, pain and function. These outcomes are highly important to patients for optimal gout management [5, 25]. Their inclusion in the provisional definition of gout disease modification confirms their key importance to the impact of the disease and its treatment. Examination of data sets in the future will help to determine whether there is a significant overlap between some of these domains or whether they contribute independently to disease modification.

The inclusion of tophi reduction/regression/prevention for defining disease modification is an important decision by the experts. Although clinicians typically observe urate tophi on clinical examination in the s.c. tissue, bursa or joint area in a minority of gout patients, intra-articular and subclinical urate tophi can be detected in a larger proportion. Advances in joint imaging with in-clinic joint US and/or dual energy CT make the detection and monitoring of tophi easier and more practical. Tophi reduction is consistent with the key aim of chronic gout treatment (i.e. the elimination of the deposited urate crystals [26]). This domain is also closely linked to total body urate burden and to the serum urate levels, highlighting the central role of serum urate in gout pathophysiology.

Joint preservation and prevention of radiographic joint damage as a disease modification criterion in gout is important. This aspect encompasses the overall impact of gout on joint structure, including both the acute and chronic inflammation that accompanies this disease. Routine use of radiographs, US and dual energy CT makes it possible for the clinician to monitor this aspect of disease progression. This might be challenging in resource-constrained settings.

This study represents an advance in achieving consensus for the concept of disease modification in gout. The availability of provisional gout remission criteria provides an important endpoint for gout trials, and treatment guidelines provide guidance for routine clinical care. One might ask what the disease modification adds to this available information. The regulatory agencies commonly use the concept of disease modification for approval for new medications for various rheumatic diseases, such as OA and RA. This paper provides a framework for what constitutes gout disease modification from the perspective of trialists and gout clinicians. More work needs to be done to define this concept further. An important next step would be to establish the thresholds for various domains of disease modification that are clinically meaningful and relevant to patients with gout. We need follow-up studies among patients with gout and health-care professionals to understand the extent to which stabilization or worsening in one or more domains is allowed, while other domains improve, for the effect of an intervention to qualify as disease modification. Another concept that needs further study is whether different thresholds or components are needed for short-term *vs* long-term disease modification, both in clinical practice and in clinical trials. Although remission is the goal for every patient, disease modification is a more practical interim goal to achieve. This construct, once defined, can certainly support the development of new pharmacological and non-pharmacological treatments for gout.

The findings must be interpreted in light of the study limitations. Although a reasonable sample size for each nominal group of three/four to seven people was planned, owing to the limited availability of these international experts and differences in time zones across three continents, some group sizes are small/smaller. The discussion in these groups might not have been as robust. It is recognized that although the virtual platform

for NGT has been used successfully instead of in-person meeting [19, 20], research studies using this method are fewer, and more evidence is needed to be confident that this is analogous to in-person NGT. It is possible that some discussions might be limited owing to lower ability to read body language and interruptions owing to being in an uncontrolled physical space.

In conclusion, this qualitative study with gout expert rheumatologists identified provisional domains for disease modification in gout. The findings are consistent with, and advance, work by the OMERACT gout group in acute/chronic gout domains and gout remission criteria [2, 5, 25]. Future studies to advance the development of consensus-based definitions and clinically meaningful thresholds for disease modification in gout are now needed.

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J.A.S. designed the study, developed the protocol, conducted the nominal sessions, analysed the voting by the participants and the data, wrote the first draft of the manuscript and revised it and made the decision to submit it.

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Data availability statement

I am ready to share the data with colleagues, after obtaining appropriate permissions from the University of Alabama at Birmingham (UAB). The data underlying this article will be shared on reasonable request to the corresponding author.

Supplementary data

Supplementary data are available at *Rheumatology Advances in Practice* online.

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