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11 **Gout flare severity from the patient perspective: a qualitative interview study**

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34 competing interests.

35 **ABSTRACT**

36 **Objective:** The patient experience of a gout flare is multi-dimensional. To establish the most
37 appropriate methods of flare measurement, there is a need to understand the complete experience
38 of a flare. This qualitative study aimed to examine what factors contribute to the severity of a flare
39 from the patient perspective.

40 **Methods:** Face-to-face interviews were conducted with people with gout. Participants were asked
41 to share their experience with their worst gout flare and contrast it to their experience of a less
42 severe or mild flare. Interviews were audio-recorded and transcribed verbatim. Data was analysed
43 using a reflexive thematic approach.

44 **Results:** Twenty-two participants with gout (17 males, mean age 66.5 years) were interviewed at
45 an academic centre in Auckland, New Zealand. Four key themes were identified as contributing to
46 the severity of a flare: flare characteristics (pain intensity, joint swelling, redness and warmth,
47 duration, and location), impact on function (including walking, activities of daily living, wearing
48 footwear, and sleep), impact on family and social life (dependency on others, social connection,
49 and work) and psychological impact (depression, anxiety, irritability, and sense of control).

50 **Conclusion:** A wide range of interconnecting factors contribute to the severity of a gout flare from
51 the patient perspective. Capturing these domains in long-term gout studies would provide more
52 meaningful and accurate representation of cumulative flare burden.

53 **Keywords:** gout, qualitative research, thematic analysis, patient reported outcomes, patient
54 experience

55 **SIGNIFICANCE AND INNOVATIONS**

56 • This is the first study to examine factors contributing to the overall severity of a flare from the
57 patient perspective.

58 • Multiple interconnected domains contribute to the overall severity of a flare; flare
59 characteristics, impact on function and activities of daily living, psychological impact and
60 impact on family and social life were the key themes.

61 • Measuring these domains in studies assessing flare management or prevention may provide
62 more meaningful and accurate representation of cumulative flare burden from the patient
63 perspective.

64 Gout flares (sometimes referred to as “gout attacks” or “acute gout”) are a characteristic feature of
65 gout and a central concern to patients [1]. An important goal in the management of gout is
66 complete suppression and prevention of gout flares. However, there is currently no standardised
67 method for the assessment of gout flares in clinical trials. Content analyses have shown a wide
68 variation in methods used to measure and report flares in clinical trials of flare prevention [2, 3].
69 The majority of studies capture data related to flare frequency, with few studies also reporting data
70 related to flare duration and pain severity [2].

71 The patient experience of a gout flare is multi-dimensional and goes far beyond the data routinely
72 captured in clinical trials. A recent meta-synthesis of qualitative studies illustrated the impact of
73 gout flares on many aspects of patients’ lives, including physical, social and family life, and
74 psychological wellbeing [4]. The interconnecting nature of these domains highlighted the
75 complexity of the flare experience, but it remains unclear which aspects of a flare are most
76 important to patients in influencing the overall flare burden.

77 Establishing meaningful flare reporting in clinical trials would involve defining the most
78 appropriate methods of gout flare measurement. An important step in achieving this is to better
79 understand, from the patient perspective, which factors make the experience of a flare more or less
80 severe. This qualitative study aimed to examine what factors contribute to the severity of a gout
81 flare from the patient perspective.

82

83 **PATIENTS AND METHODS**

84 *Participants*

85 Participants were recruited through existing databases of patients with gout who had participated
86 in research at the Clinical Research Centre, University of Auckland, New Zealand and consented
87 to be contacted for future studies. Purposive sampling was used to ensure a broad and diverse
88 representation of demographic variables (age, ethnicity, sex) and gout disease characteristics
89 (disease duration, tophaceous gout, flare frequency). Participants were included if they had gout
90 according to the 2015 ACR/EULAR Gout Classification Criteria [5]; had at least one gout flare in
91 the last 12 months; were aged ≥ 18 years, and were English-speaking. Participants were excluded
92 if they had a cognitive impairment that would preclude completion of the interview or had other
93 forms of inflammatory arthritis. Ethical approval was obtained from the University of Auckland

94 Human Participants Ethics Committee (UAHPEC 023965) and all participants provided written
95 informed consent.

96 *Data collection*

97 In-depth, semi-structured face-to-face interviews were conducted by a rheumatologist who was not
98 involved in the medical care of the participant (AG). Participants were asked to share their
99 experience of flares during the course of their disease by recalling their worst gout flare as well as
100 a less severe/mild gout flare in order to capture factors contributing to overall flare severity. An
101 interview schedule containing key focused, open-ended questions and probes was used to
102 encourage conversation. These questions included: “Can you tell me about the worst gout flare
103 you have had?”, “What was it about this flare that made it so severe?”, “Can you tell me about a
104 mild gout flare?” and “What was it about this flare that made it less severe?”. The questions and
105 probes were elicited from a meta-synthesis of qualitative studies reporting the patient experience
106 of gout flares [4].

107 The interviews took place in a private room at the Clinical Research Centre (University of
108 Auckland, New Zealand) and lasted between 20 and 45 minutes. Each interview was digitally
109 audio-recorded, transcribed ad verbatim and anonymised to ensure confidentiality. Participants
110 had the opportunity to review the transcripts to check for completeness and representativeness.

111 Demographic and clinical data were also obtained during the participants’ study visit, including
112 age at onset of gout, ethnicity, and presence and history of clinical features of gout and treatment.

113 *Data analysis*

114 Data collection and analysis occurred simultaneously, and initial results informed successive
115 sampling and data collection as themes emerged. Interviews continued until no new themes were
116 identified from the data and the purposive sampling framework was completed. Data was
117 analysed using a reflexive thematic approach [6]. Transcripts from the interviews were read and
118 re-read to immerse the researcher in the data. Emergent themes identified from the transcripts
119 were initially coded and categorized by a single researcher (AG) using NVivo software (QSR
120 International Property Ltd., Version 12). Initial codes and concepts were reviewed by two further
121 researchers (SS, IS) and final codes were then grouped into potential themes and sub-themes. The
122 researchers met regularly to discuss the data throughout the analysis stage and the final themes

123 were defined, named and agreed upon by all authors. Illustrative quotes from transcripts were
124 selected to provide evidence for each theme and subtheme.

125

126 **RESULTS**

127 **Participants**

128 A total of 22 participants with gout were interviewed. There was diversity across age, gender,
129 ethnicity and clinical features (**Table 1**).

130

131 **Themes**

132 Four key themes were identified from the data. Participants described the characteristics of the
133 flares, impact on physical function and activities of daily living, impact on social and family life
134 and psychological impact as contributing to the overall severity of a flare. Illustrative quotes are
135 shown in **Tables 2-5**. A thematic map showing the four themes and sub-themes is provided in

136 **Figure 1**.

137

138 *Gout flare characteristics*

139 Pain intensity was reported by all participants as contributing to gout flare severity. Participants
140 described pain of a severe flare as “*intense*”, “*extreme*”, “*excruciating*”, “*horrible*” and
141 “*horrendous*”. Several participants also described it as the worst pain they had ever experienced,
142 which for some was worse than a broken bone, abdominal surgery, or giving birth. The pain of a
143 severe gout flare was described as constant and unchanging with no ability to alleviate it. Many
144 participants described the intensity of pain using a numeric rating scale which varied from 6 to
145 “11” out of 10. In contrast, the pain of a mild flare was described as “*uncomfortable*” and
146 “*awkward*”. The pain of a mild flare was compared to having tight muscles, exercise-related
147 soreness, feeling very stiff, or stubbing a toe. Mild flares were described with numeric pain
148 ratings ranging from 2 to 4 out of 10.

149 A severe gout flare was also accompanied by intense joint swelling, warmth and redness.
150 Participants described worsening of these symptoms as the flare progressed. In contrast,
151 participants noted a low level or complete absence of these characteristics during mild flares.

152 Flare duration was an important factor in contributing to flare severity. Participants described a
153 severe flare as lasting multiple days and even for weeks, while mild flares resolved much more
154 quickly, sometimes within hours.

155 The location of the gout flare also influenced overall flare severity. Gout flares affecting larger
156 joints, such as the knees, created greater functional difficulty than flares in smaller joints, such as
157 the feet. Some participants also felt that flares involving joints that were easier to rest and had less
158 impact on functional activities, such as wrists, were less severe compared with flares involving
159 joints required for mobility, including feet and ankles.

160

161 ***Impact on function***

162 The level of disability also influenced overall flare severity. During severe flares, walking was
163 described as extremely difficult, or completely impossible. Performing any function involving
164 weightbearing, including standing, exacerbated the pain of the flare. Participants could be
165 completely immobile during a severe flare and had to stay seated in a chair or lying in bed, while
166 others described using a wheelchair or crawling or hopping to move around. In contrast, the ability
167 to walk was not affected to the same extent during a mild flare. Although walking was still
168 difficult and uncomfortable for some, the milder symptoms meant it was easier to move around
169 compared to a severe flare.

170 Participants described greater difficulty with activities of daily living during severe flares. Tasks
171 such as holding a mug, getting out of bed, showering, going to the toilet, and walking up and down
172 stairs were difficult during severe flares. In contrast, during mild flares participants were still able
173 to participate in most daily activities, even working out or playing golf.

174 Gout flare severity was also influenced by the ability to wear footwear. During severe flares, many
175 were unable to wear shoes at all due to the accompanying swelling and pain. Some participants
176 opted for more open-style or looser fitting shoes, such as sandals or jandals (flip-flops), or wore

177 different shoes on each foot. In contrast, during mild flares, participants were often able to wear
178 firmer, fitting sneakers, which could not be worn during a severe flare.

179 Most participants had difficulty sleeping during severe flares. The affected area was described as
180 hypersensitive. Participants described difficulty finding a comfortable position to sleep in, with
181 even the slightest movement causing pain. Pillows were used in an attempt to relieve pressure in
182 the area and find a position that was comfortable enough to sleep in. The pain would sometimes
183 wake participants up and prevent them from getting back to sleep. In contrast, during mild flares,
184 the pain did not always wake participants from sleep and participants found it easier to find
185 comfortable positions.

186

187 ***Impact on family and social life***

188 During severe flares, participants reported being dependent on others, including relying on family
189 members to bring them things around the house, asking others to drive the car, and push them in a
190 wheelchair.

191 A severe gout flare disrupted social connections, leading to physical and psychological withdrawal
192 from family and friends. During a severe flare, participants wanted to be left alone and did not
193 want to interact with their spouses or children.

194 During severe flares, many participants had to take days off work. For others who attended work,
195 they described staggering around or remaining seated. Not being able to walk or drive meant some
196 participants had no way of getting to work during severe flares. In contrast, during a mild flare,
197 participants did not have to take days off work and were able to comfortably perform sedentary or
198 computer-based tasks.

199

200 ***Psychological impact***

201 A severe flare led to feelings of helplessness and not being able to escape the pain. Participants
202 experienced depression and low mood at the time of a severe flare. Participants also reported
203 feeling anxiety and constantly worried about someone bumping them and exacerbating the pain.

204 During milder flares, participants felt anxious about whether the flare would get worse, whilst
205 other participants experienced less worry, as they knew it would get better again.

206 In a severe flare, many participants felt irritable. Not being able to do anything and having to take
207 time off work resulted in frustration. During severe flares participants also reported losing patience
208 with others and became grumpy and cranky around family members, including their children. In
209 contrast, participants described feeling only slight frustration during mild flares.

210 Another important contributor to the overall severity of flares was the sense of control. For many
211 participants, their worst gout flare was their first one because they had never experienced anything
212 like it and did not understand what was happening. Feelings of shock and an inability to control
213 the symptoms contributed to the severity of the flare. During mild flares, participants described
214 being able to sense a flare coming on. Knowing what to expect made the situation less shocking
215 and participants were able to initiate treatment quickly which also prevented the pain from
216 reaching the same peak as a severe flare.

217

218 **DISCUSSION**

219 This qualitative study provides in-depth, insights into factors which contribute to the overall
220 severity of a gout flare from the patient perspective. Although numerous studies have reported on
221 the patients' experience of flares (summarized in [4]), this is the first study to specifically examine
222 what factors contribute to the severity of a flare from the patient perspective. Flare characteristics,
223 impact on function and activities of daily living, psychological impact and impact on family and
224 social life were the key themes.

225 Pain intensity was the dominant reported flare characteristic distinguishing a severe flare from a
226 mild flare. The importance of pain is also reflected in its inclusion as a mandatory outcome
227 measure proposed by OMERACT for acute and chronic gout studies [7]. The experience of pain
228 varied greatly between severe and milder flares. In the current study, mild flares, which were
229 given ratings of between 2 to 4 on a 0- 10-point pain scale, may not all have met the recently
230 validated Gaffo definition of a flare which requires a pain rating of at least 3 [8]. This highlights
231 the variability in pain intensity of a flare which may not be comprehensively captured with a
232 binary (present/absent) definition of a flare.

233 Physical disability, including difficulty walking and performing other activities of daily living,
234 coupled with reliance on family members for assistance, were also commonly identified factors
235 influencing the perceived severity of a flare. Feelings of depression, anxiety, and irritability also
236 contributed to the overall severity of a flare. Previous research has shown associations between
237 decreased physical and mental wellbeing and flare frequency [9]. Flare frequency is also important
238 to the patient perception of being in a state of low disease activity or remission[10]. Given the
239 intermittent nature of the flare experience and the complete resolution of symptoms between
240 flares, the extent to which these factors contribute to the cumulative burden of flares over time
241 would be of interest.

242 Sense of control was an important psychological factor contributing to the patient perception of
243 flare severity. Knowledge and experience of previous flares, not present during a patients first gout
244 flare, meant patients were able to initiate treatment to control the symptoms and prevent it from
245 escalating into a more severe flare. These findings align with previous work, which has shown that
246 patients who have a greater perceived understanding of the illness report more personal- and
247 treatment-related control of the disease [11].

248 In this study, multiple domains contributed to the overall severity of a flare. These findings are
249 consistent with previous work, which has shown that the experience of a gout flare is multi-
250 dimensional with several interconnecting factors [4, 12]. However, it is unclear how much the
251 overall severity of a flare is driven by pain alone. For example, severe flares were associated with
252 greater pain intensity which then impacted on patients' ability to function, and therefore to attend
253 work and undertake usual activities, which in turn impacted psychological health. Further work is
254 warranted to determine the relative importance of factors which influence the overall severity of
255 individual flares as well as the cumulative burden of flares over time.

256 This study has a number of strengths and limitations. Firstly, the purposeful sampling method
257 ensured that participants represented a wide range of demographic and clinical features of gout
258 which provides a diverse view of different patient experiences. However, participants were
259 predominantly male, and although this reflects the sex differences in gout prevalence, this may
260 reduce generalizability of the findings to female patients with gout. A further strength was the
261 continuation of recruitment and analysis until theoretical saturation was reached, which provides
262 confidence that a comprehensive understanding of the patient perspective was covered.

263 In conclusion, this qualitative study identified four key domains that together contribute to the
264 overall severity of a gout flare from the patient perspective. In addition to flare characteristics,
265 impact on function, psychological health, and family and social life all contribute to the severity of
266 a gout flare. Measuring these domains in long-term studies assessing flare management or
267 prevention, in addition to simply measuring reductions in flare frequency, would provide more
268 meaningful and accurate representation of cumulative flare burden from the patient perspective.

269

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305

Table 1. Participant demographic and clinical characteristics (n = 22)

Gender, n (%)	
Male	17 (77%)
Female	5 (23%)
Age in years, median (range)	67 (27-84)
Ethnicity, n (%)	
NZ European	12 (55%)
Māori	5 (23%)
Asian	3 (14%)
Pacific Peoples	2 (9%)
Disease duration in years, median (range)	10.5 (6 months- 35 years)
Age at onset of gout in years, median (range)	48.5 (20-81)
Number of flares in the last 12 months, n (%)	
1-4	16 (73%)
5-9	2 (9%)
≥10	4 (18%)
Tophaceous gout, n (%)	5 (23%)
Last serum urate level, mmol/L, median (range)	0.31 (0.18-0.64)
Urate lowering therapy, n (%)	
Allopurinol	18 (82%)
Febuxostat	1 (5%)
Allopurinol + probenecid	1 (5%)
None	2 (9%)

Table 2. Quotes illustrating flare characteristics

Subtheme	Severe flares	Mild flares
Pain intensity	“[It’s] just so intense ... it’s one of the worst pains I’ve ever had. I’ve had abdominal surgery, and it’s not as bad as the gout.” (Participant 3, M, 59 years, NZ European)	“You can feel it, it’s there, but it’s not a real, serious one ... you can just sort of sense it, you know it’s there.” (Participant 6, M, 72 years, Asian)
	“I’ve had broken ankles and broken knees and joints and stuff like that and I would rate those pain as, probably, out of ten, probably up in about six, seven. But the gout would sit pretty close to a nine.” (Participant 5, M, 57 years, Māori)	“It’s somewhere more in background than in the foreground. Probably maybe more like a four out of ten, or something like that, and so you can sort of cope with it a bit more.” (Participant 11, M, 57 years, NZ European)
	“It’s like someone’s stabbing me with a bottle” (Participant 8, M, 44 years, Māori).	“It’s a bit like if you’re walking around the house in bare feet and you stub your toe—you accidentally kick a piece of furniture with your toe—and it hurts. It feels like that.” (Patient 9, M, 69 years, NZ European)
Joint swelling, redness, warmth	“When it flares up, it’s just redder and tighter than the not-so-bad ones.” (Participant 16, F, 68 years, NZ European)	“There was no redness, no nothing.” (Participant 21, F, 73 years, NZ European)
Duration	“Seven, eight days, I was in real pain, and then it subsided, bit by bit.” (Participant 10, M, 73 years, NZ)	“It’s just probably less than twenty-four hours or twenty-four hours.” (Patient 14, M, 60 years, Asian)

	European)	
Location	“It was two joints at the same time. And it was the same leg, so moving was especially hard.” (Participant 12, M, 48 years, Asian)	“But like if it’s in the side of my foot, or my toe, or you know, you can sort of manage it ... I can go to work. It’s not comfortable, but it’s tolerable, if you know what I mean?” (Participant 8, M, 44 years, Māori)
	“Depending on where it is, like, even a mild one in my knees is still...incapacitating.” (Participant 8, M, 44 years, Māori)	“I would rather have it in the wrist than in the foot. [If] it was on the wrist I could manage it more. I mean, with your foot, I’m not, like, flexible, so it’s hard to do anything with it. With the wrist, it’s just much, much easier, ‘cause I can rest it anywhere.” (Participant 12, M, 48 years, Asian)

Table 3. Quotes illustrating the impact on physical function and activities of daily living

Subtheme	Severe flares	Mild flares
Walking ability	“I thought that using a [walking] stick might help to walk around; it didn’t help anything.” (Participant 18, F, 61 years, Māori).	“It is a bit sore, but I can still walk and move around. It’s a bit easier to manage.” (Participant 17, M, 27 years, Pacific Island)

	<p>“I had to ask the person that takes the wheelchair people if I could get a ride – I couldn’t walk.” (Participant 4, M, 59 years, Māori).</p>	<p>“Walking becomes a little bit more difficult, but not impossible.” (Patient 7, M, 82 years, NZ European)</p>
	<p>“I had trouble driving. [It] was difficult changing gear in a right-hand drive car. So you're changing gear with your left hand.” (Participant 1, M, 74 years, NZ European)</p>	<p>“You can’t go right back to normal lifestyle, but you can do things, more things, than [if] it was severe.” (Participant 19, M, 30 years, Pacific Island)</p>
Impact on activities of daily living	<p>“When it’s at its worst, I [wasn’t] able to move my arm ... it was difficult to even just get out of bed... shower, toilet. All those daily things, it was just, pretty much, very difficult.” (Participant 19, M, 30 years, Pacific Island)</p>	

Ability to wear footwear	<p>“It makes it very difficult to put proper shoes on, you’ve got to then go to a sandal-type thing until it reduces” (Participant 21, F, 77 years, NZ European)</p>	<p>“Sneakers – they’re alright when it’s mild – you sort of feel like maybe it’s just keeping [the foot] still. Whereas you can’t stand it being firm when it’s really bad.” (Participant 16, F, 68 years, NZ European)</p>
Impact on sleep	<p>“When it hits hard, you can’t even put a sheet over because it hurts at night. And if you move at night it just hurts, so you keep waking up” (Participant 12, M, 48 years, Asian)</p> <p>“In bed, at night-time... it’ll be throbbing and aching and hot. It makes it harder to get off to sleep.” (Participant 20, F, 84 years, NZ European)</p>	<p>“When it’s [not] really bad, usually you can sleep, get in a position where it’s comfortable and you’re not feeling anything” (Participant 8, M, 44 years, Māori).</p>

Table 4. Quotes illustrating the impact on family and social life

Subtheme	Severe flares	Mild flares
Dependency on others	<p>“I was dependent on mum and dad, and just my little sisters to get me things around the house.” (Participant 17, M, 27 years, Pacific Island)</p> <p>“I remember my wife driving the car for me”</p>	<p>No relevant quotes.</p>

	(Participant 15, M, 78 years, NZ European)	
Social connection	“I’ll withdraw from my engagement with family and friends and what I might be doing, and so, they’ll notice that you’re off the grid.” (Participant 11, M, 57 years, NZ European)	No relevant quotes.
Impact on work	“I had to take a week off. Oh, four and a half days off work. Lucky I have an understanding boss” (Participant 12, M, 48 years, Asian)	“I can still go to work; it’s still not ideal or comfortable, but I don’t have to waste a sick day on not going” (Participant 8, M, 44 years, Māori). “Never had to take days off with a mild one” (Participant 17, M, 27 years, Pacific Island)

Table 5. Quotes illustrating psychological impact

Subtheme	Severe flares	Mild flares
Depression	“I felt horrible. I’ve been suicidal ... and when I got the gout it played around with my mind.” (Participant 18, F, 61 years, Māori)	“No [it didn’t impact my mood]. I had come to accept it for what it was.” (Participant 2, M, 65 years, NZ European)
Anxiety	“You’re all the time worrying about not hitting it against something or somebody just bumping you.” (Participant 16, F, 68 years, NZ European)	No relevant quotes.
Irritability	“[With a severe flare] you don’t have a lot of patience, even the cat kept away from me.” (Participant 9, M, 69 years, NZ European)	No relevant quotes.
Sense of control	“Just knowing that it’s out of my control – like, no matter how much meds I take, doesn’t really mean that it will stop the flare” (Participant 17, M, 27 years, Pacific Island).	“All the others I knew instantly what it was ... I could feel it coming on... and so I got on the drugs as quickly as I could.” (Participant 2, M, 65 years, NZ European)

FIGURE LEGENDS

Figure 1. Mind map representing the four key themes and subthemes contributing to the overall severity of a gout flare.

