



# Gout and chronic pain in older adults: a Medicare claims study

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## Abstract

To assess if gout is associated with a higher risk of incident chronic pain. This study used the 2006–2012 Medicare claims data. We used multivariable-adjusted Cox regression analyses to examine the association of pre-existing diagnosis of gout with incident (new) diagnosis of chronic pain, adjusting for demographics, medical comorbidity, and use of common medications for cardiovascular disease and gout. Sensitivity analyses substituted Charlson-Romano score with a categorical variable or each Charlson-Romano comorbidity. There were 1,321,521 eligible people, of whom 424,518 developed incident chronic pain. Crude incidence rates of chronic pain were as follows: gout, 158.1 per 1000 person-years and no gout, 64.5 per 1000 person-years. In multivariable-adjusted Cox regression analyses, gout was associated with higher hazard ratio of chronic pain, 2.02 (95% CI, 1.98, 2.05), confirmed in sensitivity analyses 1.96 (95% CI, 1.93, 1.99) (model 2) and 1.77 (95% CI, 1.74, 1.80) (model 3). No meaningful differences were found by gender and race in subgroup analyses; slightly lower hazard of chronic pain with gout was seen in oldest people. Use of allopurinol or febuxostat was associated with lower risk of chronic pain, 0.79 (95% CI, 0.77, 0.82; model 1) and 0.72 (95% CI, 0.56, 0.92; model 1). Gout was associated with a doubling of the risk of chronic pain and gout treatments with reduction in the risk. Efforts must be made to optimize gout control, so that chronic pain can be avoided as a long-term sequelae of gout and when present, treated early and appropriately.

## Key points

- Gout was associated with twofold higher risk of incident (or new) diagnosis of chronic pain.
- Gout treatments were associated with a lower chronic pain risk.
- Increased risk of chronic pain with gout was similar across age, race, and sex.
- Studies should examine if optimal gout control with treat-to-target approach can reduce the risk of chronic pain in people with gout.

**Keywords** Chronic pain · Elderly · Gout · Older adults · Risk

## Abbreviations

ICD-9-CM	International Classification of Diseases, ninth revision, common modification	CAD	coronary artery disease
XOR	xanthine oxido-reductase system	ACE inhibitor	angiotensin converting enzyme inhibitor
		ULT	urate-lowering therapy
		CMS	Centers for Medicare and Medicaid Services

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## Introduction

Chronic pain is common and it affects 20% of the European population [1] and 30% of the adult US population [2]. Chronic pain is more common in women, older people, and in people with lower socioeconomic status, depression and psychological comorbidity, and history of abuse or interpersonal violence [1, 3]. Chronic pain accounts for annual societal cost of \$150 billion in the USA and €200 billion in Europe [4]. Chronic pain leads to physical and emotional burden and a negative impact on physical, emotional, and social well-being [5]. Chronic pain is associated with limitation of sleep, exercise, the ability to do household chores, social activities, and being independent [6]. Thus, chronic pain constitutes a major healthcare and societal burden.

In the European survey of 4292 patients with chronic pain, osteoarthritis and rheumatoid arthritis were two of the top five causes of chronic pain [6]. Osteoarthritis and rheumatoid arthritis were the most common cause of chronic pain (42% combined), followed by degenerated or herniated disc [6], confirming the population-level contribution of these conditions to chronic pain. A major limitation was that gout was not included in this population-level study of chronic pain.

Gout is the most common inflammatory arthritis in adults and is four-times as prevalent as rheumatoid arthritis [7]. The 2017 American College of Physicians (ACP) treatment guideline for gout emphasized a treat-to-symptoms (T2S) approach consistent with a view that gout is mostly an intermittently symptomatic condition, rather than a chronic disease [8]. This attempt to re-define a chronic disease is unnecessary. Gout is a chronic disease based on disease pathophysiology [9]. Interestingly, patients with gout frequently cited flares as the main or sometimes the only way their gout bothered them [10]. This raises the question: does gout lead to chronic pain (above and beyond intermittent gout flare-related pain)? Our study objective was to address this question using data from older Americans who were Medicare beneficiaries. We assessed the crude incidence rates of chronic pain, and whether gout was independently associated with chronic pain.

## Methods

### Data sources and study sample

We used the 5% random sample of 2006–2012 Medicare claims to conduct this study. People were eligible to be included in the current study, if beneficiaries were currently enrolled in Medicare fee-for-service (parts A, B), not enrolled in Medicare part C [Medicare advantage plan, which leads to incomplete claims]) and lived in the USA during the period 2006–2012. The Institutional Review Board at the University of Alabama at Birmingham approved the study.

## Independent variable of interest and covariates

Presence of gout at baseline, identified by two claims at least 4 weeks apart, containing an International Classification of Diseases, ninth revision (ICD-9-CM), 274.xx, was the independent variable of interest. This is a valid approach to identifying gout with specificity and sensitivity of  $\geq 90\%$  [11] and with positive predictive values, sensitivity, and specificity of 86%, 95%, and 86% [12].

We included potential confounders as covariates and adjusted for them in the analyses. Patient demographics, age, sex, and race were included, and data were obtained from the Medicare denominator file and the beneficiary summary file. We assessed medical comorbidity using the Charlson-Romano comorbidity index, a validated measure of comorbidity, developed for claims data [13], treated as a continuous variable, obtained from inpatient and outpatient Medicare claims. We used prescription claims from Medicare part D file to obtain data on the use of the common cardiovascular drugs (statins, beta-blockers, diuretics, and angiotensin converting enzyme (ACE)-inhibitors) and drugs for gout (allopurinol, febuxostat). These drugs were surrogates for the severity (and the presence) of the underlying conditions they were used to treat.

## Dependent variable/outcome of interest

The predictor of interest was incident (new) chronic pain, with an absence of this diagnosis in the baseline period of  $\geq 1$  year, that occurred in patients with or without pre-existing gout diagnosis that preceded the diagnosis of chronic pain. We identified chronic pain by the occurrence of at least two claims 4 weeks apart containing any of the following ICD-9-CM codes as tested previously [14]: 307.80, 307.89, 338.0, 338.2, 338.4, 719.41, 719.45–719.47, 719.49, 720.0, 720.2, 720.9, 721.0–721.4, 721.6, 721.8, 721.9, 722, 723.0, 723.1, 723.3–723.9, 724.0–724.6, 724.70, 724.79, 724.8, 724.9, 729.0–729.2, 729.4, 729.5 (details, Table 1). This is a valid approach, with positive predictive value of 95%, sensitivity of 70%, and specificity of 99% [15].

## Statistical analyses

Crude incidence rates were calculated for occurrence of a new diagnosis of chronic pain in patients with vs. without gout at baseline. Characteristics of people with vs. without incident chronic pain were compared using *t* test or chi-square test, as appropriate. We used multivariable-adjusted Cox proportional hazard model to assess whether gout diagnosis at baseline was associated with a diagnosis of incident chronic pain (i.e., a new diagnosis) during the follow-up, while adjusting for demographics, comorbidity, and common medications (model

1). Sensitivity analyses modeled Charlson-Romano index in categories (model 2) or as individual comorbidities (model 3).

## Results

### Demographic and clinical characteristics of study population

There were 1,321,521 eligible people, of whom 424,518 developed incident chronic pain (Table 1). Compared to people without incident chronic pain, those with incident chronic pain were older, had higher Charlson-Romano comorbidity index score, and were more likely to be female, White, or have hypertension, hyperlipidemia, or coronary artery disease (Table 1). Crude incidence rates of chronic pain were as follows: people with gout, 158.1 per 1000 person-years and people without gout, 64.5 per 1000 person-years.

### Multivariable-adjusted association of gout with chronic pain

After adjustment for demographics, comorbidity, and medications, compared to people without gout, those with gout were twice as likely to develop incident chronic pain; HR was 2.02 (95% CI, 1.98, 2.05) (Table 2). In sensitivity analyses that substituted Charlson-Romano score with categorical variable or each Charlson-Romano comorbidity, the hazard ratios of incident chronic pain were minimally attenuated to 1.96 (95% CI, 1.93, 1.99; model 2) and 1.77 (95% CI, 1.74, 1.80; model 3) (Table 2). Use of gout treatments was associated with lower risk of chronic pain (Table 2). In a priori defined subgroup analyses by age, gender, and race, we noted minimal clinical differences in the hazard ratios, except for slight reduction in association of gout with incident chronic pain with older age, from HR of 2.20 (95% CI, 2.15, 2.25) in 65–<75-year-old people to 1.75 (95% CI, 1.67, 1.85) in >85 years old (Table 3). All interaction terms were statistically significant, consistent with a large sample size (Table 3).

## Discussion

Our study demonstrated that a current diagnosis of gout was associated with a 2.1-fold higher risk of a new diagnosis of chronic pain during the follow-up. This estimate was robust and changed minimally 1.8–2.0 in sensitivity analyses. Gout affects 3.9% of the US adult population or 8.3 million Americans according to an NHANES study [7]. Gout is more prevalent in the population than rheumatoid arthritis, which affects <1% US population [16]. Interestingly, rheumatoid arthritis together with osteoarthritis were the most common causes of chronic pain (42%) in a European survey of 4292 patients with

chronic pain [6]. However, gout was not examined among the top 34 suspected reasons for chronic pain. This omission may be due to feasibility [6]; however, it is consistent with myths, biases, and misbeliefs that gout does not cause chronic pain.

Our finding of a doubling of the risk of chronic pain, associated with gout in a representative sample of older Americans, is consistent with the clinical presentation of gout [9]. This finding will hardly surprise most clinicians caring for people with gout. The risk/hazard of chronic pain associated with gout was somewhat surprising, since we predicted a hazard ratio of 1.3–1.5 of chronic pain. Our study finding does not imply that every gout patient will have chronic pain or that chronic pain occurs with all disease durations or disease severity. We found no meaningful differences in the association of gout with chronic pain by race or gender. Association of gout with chronic pain was slightly weaker with increasing age, from HR of 2.23 in 65–<75-year-old people to 1.84 in >85 years old, although some might appropriately question whether hazard ratio of 2.2 differs from 1.8.

Wide-spread misinformation exists with regard to gout. The recent ACP gout guideline was titled “Management of Acute and Recurrent gout”, noting that “in some patients, the frequency and duration of acute attacks increase over time and lead to chronic gout...”, and suggested a treat-to-symptom rather than a treat-to-disease-target approach for gout management. This approach mischaracterizes gout, a chronic disease associated with joint and systemic inflammation, as an intermittent disease [8]. Patients in nominal groups referred to gout flares as “gout” and chronic joint pain due to chronic inflammatory gouty arthritis as “my arthritis,” based on the misinformation that gout does not cause arthritis [10]; many patients commented “gout doesn’t cause arthritis, not that I know of”. In 2018, both patients suffering from consequences of this chronic disease and clinicians who provide care for gout are still confused about the true nature of gout, a chronic disease interrupted by acute flares, similar to heart failure or chronic obstructive pulmonary disease (COPD). Just as COPD or heart failure are lifelong chronic diseases, where the disease and associated pathophysiology exist between flare-ups; gout, associated pathology, and its effect on the various organ systems including the joints are chronic, which do not magically disappear between flares. Obviously, the severe acute pain associated with intermittent gout flares may dominate the early disease. But untreated and suboptimally treated gout with chronic synovitis and systemic inflammation will dominate the quality of life impacts and associated cardiometabolic and renal disease during a patient’s lifetime. A chronic disease such as gout needs treatment of the underlying abnormality, and not symptomatic treatment only. We noted that the use of allopurinol or febuxostat (ULTs for the treatment of gout) were each associated with 16–28% reduction in the risk of chronic pain, depending on the model used. This suggests that well-treated patients with gout are likely to have a lower risk of chronic pain.

Our study findings must be interpreted considering several limitations. First, there is a potential for non-differential

**Table 1** Demographic and clinical characteristics of people with vs. without a diagnosis of incident chronic pain

	Entire cohort	Incident chronic pain* during the follow-up		<i>p</i> value <sup>‡</sup>
		No	Yes	
Total, <i>N</i>	1,321,521	897,003	424,518	
Age, mean (SD)	75.2 (7.7)	75.4 (7.9)	74.7 (7.3)	<0.0001
Sex, <i>N</i> (%)				<0.0001
Male	598,257 (45.3%)	421,464 (47.0%)	176,793 (41.6%)	
Female	723,264 (54.7%)	475,539 (53.0%)	247,725 (58.4%)	
Race/ethnicity, <i>N</i> (%)				<0.0001
White	1,129,331 (85.5%)	759,840 (84.7%)	369,491 (87.0%)	
Black	113,739 (8.6%)	81,028 (9.0%)	32,711 (7.7%)	
Other/unknown	78,451 (5.9%)	56,135 (6.3%)	22,316 (5.3%)	
Charlson-Romano comorbidity score, mean (SD)	765.988 (58.0%)	549,843 (61.3%)	216,145 (50.9%)	<0.0001
Charlson-Romano score	119,833 (9.1%)	69,073 (7.7%)	50,760 (12.0%)	
0	435,700 (33.0%)	278,087 (31.0%)	157,613 (37.1%)	
1	1.42 (2.32)	1.40 (2.42)	1.46 (2.10)	<0.0001
≥ 2				
Charlson-Romano comorbidities				
Myocardial infarction	46,375 (3.5%)	31,131 (3.5%)	15,244 (3.6%)	0.0004
Heart failure	137,829 (10.4%)	94,814 (10.6%)	43,015 (10.1%)	<0.0001
Peripheral vascular disease	104,813 (7.9%)	70,707 (7.9%)	34,106 (8.0%)	0.003
Cerebrovascular disease	110,461 (8.4%)	71,901 (8.0%)	38,560 (9.1%)	<0.0001
Dementia	58,330 (4.4%)	44,098 (4.9%)	14,232 (3.4%)	<0.0001
Chronic pulmonary disease	178,860 (13.5%)	115,719 (12.9%)	63,141 (14.9%)	<0.0001
Connective tissue disease	25,397 (1.9%)	15,773 (1.8%)	9624 (2.3%)	<0.0001
Peptic ulcer disease	19,976 (1.5%)	12,976 (1.4%)	7000 (1.6%)	<0.0001
Mild liver disease	5681 (0.43%)	3766 (0.42%)	1915 (0.45%)	0.01
Diabetes	215,066 (16.3%)	132,260 (14.7%)	82,806 (19.5%)	<0.0001
Diabetes with end organ damage	58,270 (4.4%)	37,741 (4.2%)	20,529 (4.8%)	<0.0001
Hemiplegia	9174 (0.69%)	6698 (0.75%)	2476 (0.58%)	<0.0001
Renal failure/disease	40,619 (3.1%)	28,212 (3.1%)	12,407 (2.9%)	<0.0001
Any tumor, leukemia, lymphoma	121,504 (9.2%)	76,175 (8.5%)	45,329 (10.7%)	<0.0001
Moderate or severe liver disease	1447 (0.11%)	1095 (0.12%)	352 (0.08%)	<0.0001
Metastatic cancer	13,702 (1.0%)	10,658 (1.2%)	3044 (0.72%)	<0.0001
AIDS	404 (0.03%)	262 (0.03%)	142 (0.03%)	0.19
Hypertension	554,843 (42.0%)	330,934 (36.9%)	223,909 (52.7%)	<0.0001
Hyperlipidemia	392,717 (29.7%)	222,389 (24.8%)	170,328 (40.1%)	<0.0001
Coronary artery disease	198,599 (15.0%)	122,949 (13.7%)	75,650 (17.8%)	<0.0001
Obesity <sup>f</sup>	20,334 (1.5%)	12,157 (1.4%)	8177 (1.9%)	<0.0001

*SD*, standard deviation

For incident chronic pain a baseline clean period of 365 days was needed without a diagnosis of chronic pain

\*Incident chronic pain was detected based on a validated approach with positive predictive value of 95%, sensitivity of 70% and specificity of 99%, based on the presence of the following ICD-9-CM codes [14, 15]: 307.80, 307.89, 338.0, 338.2, 338.4, 719.41, 719.45–719.47, 719.49, 720.0, 720.2, 720.9, 721.0–721.4, 721.6, 721.8, 721.9, 722, 723.0, 723.1, 723.3–723.9, 724.0–724.6, 724.70, 724.79, 724.8, 724.9, 729.0–729.2, 729.4, 729.5

Psychogenic pain, site unspecified (307.80)

Other pain disorders related to psychological factors (307.89)

Central pain syndrome (338.0)  
 Chronic pain (338.2)  
 Chronic pain syndrome (338.4)  
 Pain in joint, shoulder region (719.41)  
 Pain in joint, pelvic region and thigh; Pain in joint, lower leg; Pain in joint, ankle and foot (719.45–719.47)  
 Pain in joint, multiple sites (719.49)  
 Ankylosing spondylitis (720.0)  
 Sacroiliitis, not elsewhere classified (720.2)  
 Unspecified inflammatory spondylopathy (720.9)  
 Cervical spondylosis without myelopathy; Cervical spondylosis with myelopathy; Cervical spondylosis without myelopathy; Thoracic or lumbar spondylosis with myelopathy (721.0–721.4)  
 Ankylosing vertebral hyperostosis (721.6)  
 Other allied disorders of spine (721.8)  
 Spondylosis of unspecified site (721.9)  
 Intervertebral disc disorders (722)  
 Spinal stenosis in cervical region (723.0)  
 Cervicalgia (723.1)  
 Cervicobrachial syndrome (diffuse), Brachial neuritis or radiculitis NOS; Torticollis, unspecified; Panniculitis specified as affecting neck; Ossification of posterior longitudinal ligament in cervical region; Other syndromes affecting cervical region; Unspecified musculoskeletal disorders and symptoms referable to neck (723.3–723.9)  
 Spinal stenosis other than cervical, Pain in thoracic spine, Lumbago, Sciatica, Thoracic or lumbosacral neuritis or radiculitis, unspecified, Backache, unspecified, Disorders of sacrum (724.0–724.6)  
 Unspecified disorder of coccyx (724.70)  
 Other disorders of coccyx (724.79)  
 Other symptoms referable to back (724.8)  
 Other unspecified back disorders (724.9)  
 Rheumatism, unspecified and fibrositis; Myalgia and myositis, unspecified; Neuralgia, neuritis, and radiculitis, unspecified (729.0–729.2)  
 Fasciitis, unspecified (729.4)  
 Pain in limb (729.5)

† Obesity was defined as the presence of the ICD-9-CM code, 278.0

‡ Variables were compared using *t* test for continuous or chi-square test for categorical variables



current approach for several reasons: (a) ULT discontinuation rates in gout are high, that would lead to misclassification bias [18]; (b) selection bias (due to the inclusion of ULT indicating more symptomatic, severe, or longer disease) in cohort definition due to the restriction of patient population to more severe cases, biasing towards finding a false positive association; (c) generalizability would be limited only to gout patients using ULT; and (d) a reasonable validity of the ICD-9 only approach, based on two studies [11, 12], although disagreements exist [19]. Despite our attempt to control for several confounders and covariates associated with chronic pain, residual confounding is still possible, given the observational study design. Our findings are only generalizable to Americans 65 years or older; generalizability to other populations may not be appropriate. We used a previously validated ICD-9-CM approach to identify outcome, incident chronic pain [14, 15]; however, this approach may be considered to be non-specific by some, since this definition includes rheumatic diseases and spinal disorders, among other conditions of chronic pain. Obesity was defined as the presence of the ICD-9-CM code, 278.0, given the absence of body mass index data in Medicare claims; we are well-aware that this approach grossly underestimates the prevalence of obesity. Study strengths include a large sample size, representative patient population, addressing a clinically important question, and robustness of study results. Comparison with other conditions such as rheumatoid arthritis would be interesting, but is beyond the scope of this study.

In conclusion, we found that older adults with gout suffer from chronic pain more than those without gout. Gender and race were not important modifiers of the association of gout with chronic pain. These findings support the chronic nature of gout. ULTs, allopurinol and febuxostat, were each associated with a lower risk of chronic pain. Future studies should explore, if optimal and/or early treatment of gout with ULT in people can reduce their risk of developing chronic pain. Such evidence can lend further support to the recommended treat-to-target approach in gout.

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**Author contributions** JAS designed the study, developed the study protocol, reviewed the analyses, and wrote the first draft of the paper. DC performed the data abstraction and data analyses. All authors revised the manuscript, read, and approved the final manuscript.

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**Data availability** These data can be obtained from the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data

Warehouse. We are ready to share the data with colleagues, after obtaining appropriate permissions from the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse and the University of Alabama at Birmingham (UAB) Ethics Committee, related to HIPAA and Privacy policies.

## Compliance with ethical standards

**Conflict of interest** JAS has received consultant fees from Crealta/Horizon, Fidia, UBM LLC, Medscape, WebMD, the National Institutes of Health and the American College of Rheumatology. JAS owns stock options in Amarin pharmaceuticals and Viking therapeutics. JAS is a member of the executive of OMERACT, an organization that develops outcome measures in rheumatology and receives arms-length funding from 36 companies. JAS is a member of the Veterans Affairs Rheumatology Field Advisory Committee. JAS is the editor and the Director of the UAB Cochrane Musculoskeletal Group Satellite Center on Network Meta-analysis. JAS previously served as a member of the following committees: member, the American College of Rheumatology's (ACR) Annual Meeting Planning Committee (AMPC) and Quality of Care Committees, the Chair of the ACR Meet-the-Professor, Workshop and Study Group Subcommittee, and the co-Chair of the ACR Criteria and Response Criteria subcommittee. DC has no conflicts to declare. There are no non-financial competing interests for any of the authors.

**Ethics/IRB approval and consent to participate** The University of Alabama at Birmingham's Institutional Review Board approved this study and all investigations were conducted in conformity with ethical principles of research. The IRB waived the need for informed consent for this study.

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

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