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Validation of Claims-Based Algorithms for Gout Flares

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Abstract

Purpose—Gout is a common inflammatory arthritis characterized by repeated acute flares. The ability to accurately identify gout flares is critical for comparative effectiveness studies of gout treatments. We developed and examined the accuracy of a claims-based algorithm to identify gout flares.

Methods—Patients receiving care at an academic medical center between 2006 and 2010 with a diagnosis of gout or hyperuricemia were selected using an electronic medical record-Medicare claims linked dataset. Gout flares were identified by several claims-based algorithms using a diagnosis of gout combined with gout-related medication claims and/or procedure codes for arthrocentesis or joint injection. We calculated positive predictive value (PPV) of these algorithms based on physician documentation of gout flare in medical record as the gold standard. Negative predictive value (NPV) of the gout flare algorithm was calculated in a randomly selected subgroup of 200 patients with gout.

Results—Among 3,952 subjects with gout or hyperuricemia, 503 flares were identified using the medication-based algorithm, and 290 were identified using the procedure-based algorithm. The PPV for gout flares ranged from 50–54% for the medication-based algorithms and 59–68% for the procedure-based algorithms. The NPV of the algorithm combining both medication and procedure claims was high (85.2%).

Conclusion—Use of gout diagnosis codes in combination with medication dispensing or procedure codes did not appear to accurately capture gout flares in patients with gout in a claims database. However, the claims-based flare algorithm could be useful in identifying a cohort of gout patients with no flares.

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Keywords

Gout; gout flare; comparative effectiveness; claims data

INTRODUCTION

Gout is a common inflammatory arthritis secondary to the deposition of monosodium urate crystals in the joint space. Gout has a rising prevalence and is reported to affect some 8.3 million adults in the United States[1]. A hallmark of gout is acute, repeated, attacks or flares of painful arthritis, which results in visits to health care providers and loss of productivity. The economic burden of gout in the U.S. is estimated at over 6 billion dollars with higher cost accrued by those with more frequent flares [2,3]. Identifying gout flares is an important component to clinical trial endpoints and clinically relevant as a measurement of disease control [4,5]. Gout flares are an indication for urate lowering therapies and have been included as a quality measure in the Rheumatology Informatics System for Effectiveness (RISE) Registry as well as the National Quality Forum (NQF).

The treatment of acute gout targets the inflammatory response. Nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are widely regarded as first line agents, though oral glucocorticoids are used in those with contraindications or intolerances to NSAIDs or colchicine. Intra-articular glucocorticoids can be particularly useful in the management of monoarticular gout flares[6].

Over the past few decades, large administrative claims databases have been increasingly used to study the effectiveness or safety of drugs in a real world setting. Such studies rely on the accurate identification of disease or outcomes of interest in the claims data. To date, a few claims-based algorithms to identify patients with a diagnosis of gout, not limited to flare, have been developed and tested with varied results. Two prior studies demonstrated poor performance of claims-based algorithms in identifying gout diagnoses when compared to medical record review[7,8]. One group found diagnosis codes to have a moderate positive predictive value (PPV) of 61% for gout diagnosis[7], while the second using the Veteran Affairs database reported that only 36% of patients identified by diagnosis codes met the American Rheumatism Association 1977 criteria for gout [8,9]. In contrast, a more recent study again using the Veterans Affairs database, demonstrated that diagnosis claims accurately identified gout-related visits with a PPV of 86%, in a cohort of patients with gout [10].

Several studies have used claims-based algorithms to identify gout flares. Sarawate *et al* identified gout flares through a combination of diagnosis codes for gout or joint pain and one or more of the following procedure or pharmacy codes within 1 week, intra-articular aspiration or injection, joint fluid microscopy, claim for NSAID, colchicine, corticosteroid, or adrenocorticotropic hormone [11]. Wu *et al* applied a similar algorithm but did not include joint fluid microscopy and considered gout flare in a diagnosis code for joint pain only if a claim for colchicine was made within 1 week [12]. A recent study modeled after these algorithms included a diagnosis code for gout with a pharmacy claim or medical claim with procedure code for NSAIDs, colchicine, or cortiscosteroids or a procedure code for joint

aspiration. A code for joint pain was considered a gout flare if a prescription drug claim or medical claim with procedure code was made for colchicine within 7 days[13]. While claims-based algorithms for gout flares have been used in the literature for the past several years, to our knowledge these algorithms have not been validated.

A validated claims-based algorithm identifying gout flares would allow for large-scale comparative effectiveness studies of gout treatment. The aim of this study was to develop and validate a claims-based algorithm to identify gout flares using claims data from Medicare linked with an electronic medical record (EMR) database in an academic medical center. Our EHR has been in use for 10 years and is inclusive of the general population making a valuable resource for validation studies.

METHODS

Source Population

Using data from the Brigham and Women's Hospital's EMR database linked with Medicare claims data from the Centers for Medicare & Medicaid Services (CMS), we selected a cohort of patients with an International Classification of Diseases, Ninth Revision (ICD-9) code for gout or hyperuricemia during the period between 2006 and 2010. Eligible patients were aged 65 years or older who received either inpatient or outpatient care at Brigham and Women's Hospital (Boston, MA) and were enrolled in Medicare Part A (hospital insurance), B (medical insurance), and D (prescription drug insurance) during the study period. This study was approved by the Brigham and Women's Hospital's Institutional Review Board.

Gout Flare Algorithms

We developed and tested several algorithms to identify acute gout flares using a combination of diagnosis codes (i.e., ICD-9 codes), medication dispensing claims, and procedure codes (see Table 1). First, the 'medication-based algorithm' defined flares as having at least one ICD-9 code for gout from any outpatient, inpatient or emergency department visit and a dispensing of gout-related medications for management of flare including colchicine, NSAIDs, selective cox-2 inhibitors, or oral glucocorticoids within 7 days from the date of gout diagnosis. This algorithm was run for each medication class separately and in combination. Second, the 'procedure-based algorithm' defined flares as having at least one ICD-9 code for gout from any outpatient, inpatient or emergency department visit and a procedure code for glucocorticoid injection or arthrocentesis based on J codes or current procedural terminology (CPT) codes within 7 days from the date of gout diagnosis. In addition, we used another procedure-based algorithm that required having an ICD-9 code for gout and a procedure code for glucocorticoid injection or arthrocentesis on the same date. For all above algorithms, whichever claim for ICD-9, medications, or procedures occurred second was defined as the date of gout flare (i.e. index date).

In a secondary analysis we examined the performance of the medication-based algorithm exclusively in the outpatient setting. We selected patient encounters which had at least one ICD-9 code for gout from any outpatient visit and a dispensing of gout-related medications

for management of flare including colchicine, NSAIDs, selective cox-2 inhibitors, or oral glucocorticoids within 7 days from the date of gout diagnosis.

In order to calculate a negative predictive value (NPV) for the flare algorithms, we randomly selected from the initial cohort of patients with gout or hyperuricemia a sample of 200 patient encounters where there was an outpatient, inpatient or emergency department ICD-9 code for gout but not any of the medication- or procedure-based claims outlined above. This subgroup would theoretically consist of patients with visit encounter related to gout but not to gout flare. We did not exclude patients who may have had medication or procedure based claims in the past, rather we limited analysis to those without medication or procedure claim in the 7 days before or after an ICD-9 code for gout. The index date of these random 200 encounters was the date of the ICD-9 code for gout visit.

Patients were required to have at least 30 days of continuous Medicare enrollment before and after the index date. Table 1 presents the list of ICD-9 codes for gout, gout-related medications and procedure codes used in the algorithms. As allopurinol, probenecid and febuxostat are primarily used for chronic gout management and not generally initiated as monotherapy in the acute flare setting, these medications were not included in the medication-based algorithm for flares.

Medical Record Review

For patients identified as having flares by the aforementioned medication-based or procedure-based algorithms, we conducted manual medical record review in the Brigham and Women's Hospital's EMR system. Physician documentation of acute gout attack or flare in the assessment portion of a clinical visit note within the 7 days before and after the index date was used as the gold standard. The preceding and proceeding 7 days were used as this was felt to be a reasonable time frame for documentation of visits and management. All charts were reviewed by a Rheumatology Fellow-in-training (LM) who decided whether gout flares were most probable based on documenting physician's assessment, clinical presentation and exam if available were used for decision support. Information on uric acid values and monosodium urate crystal confirmation were extracted when available in the medical record. We also collected information on whether patients had a history of gout any time prior to the index date based on any documentation or mention of gout in the clinical record. Patients with gout but without evidence of acute flare in the medical record were considered as "prevalent gout". If no documentation was found in the medical record in the 7 days before or after the index date the event was included in the analysis and marked as not having gout flare. Due to variation in detail and limitations of physician documentation in the medical record, we were unable to use criteria such as the American Rheumatism Association 1977 criteria or the newer criteria stemming from the Study for Updated Gout Classification Criteria to define gout flare or gout [9,14].

Statistical Analysis

We assessed characteristics of the study cohort using means and percentages. The PPV was calculated as the percentage of gout flares confirmed by medical record review among all the flares identified by the respective algorithm. The NPV was the percentage of visits without

mention of gout attack or flare in the physician assessment on medical record review of the index date. Ninety-five percent confidence intervals of the PPV for each algorithm and NPV were calculated by using the normal approximation of the binomial distribution. All analyses were performed using SAS 9.3 statistical software (SAS Institute Inc., Cary, NC).

RESULTS

There were a total of 3952 patients with gout or hyperuricemia in the cohort, from this cohort a total of 503 flares were identified through the medication-based algorithm, and 290 flares through the procedure-based algorithm. The mean age [standard deviation (SD)] in the medication-based algorithm was 75.4 (7.7) years and 39% were female. The mean age (SD) in the procedure-based algorithm was 76.3 (7.8) years, and 32% were female. In the medication-based algorithm limited to outpatient encounters (n=75) the mean age (SD) was 70.1 (11.1) years and 40% were female. Table 2 outlines the baseline characteristics for each flare algorithm. In the randomly selected 200 patients identified for the NPV algorithm, the mean age (SD) was 73.5 (10.1) years and 44% were female. Only a minority of flares, 5–38%, in each algorithm were confirmed by presence of monosodium urate crystals.

For the medication-based claims, the PPV [95% confidence interval (CI)] of any gout-related medication was 53.3% (95% CI 48.9, 57.7), for colchicine claim 54.0% (95% CI 48.4, 59.6), for NSAID or selective cox-2 inhibitor claim 50.0% (95% CI 42.6, 57.4), and for glucocorticoid claim 53.7% (95% CI 47.8, 59.7). When limited to outpatient encounters only, the PPV of the medication-based claim algorithm was 56.0% (95% CI 44.8, 67.2). For the procedure-based claim the PPV was 59.3% (95% CI 53.7, 65.0), and 68.4% (95% CI 61.9, 74.9) if the diagnosis and procedure code were recorded on the same day. The PPV for prevalent gout was in the 90% range for all algorithms in this cohort with pre-defined gout and hyperuricemia. Table 3.

The NPV of the algorithm combining both medication and procedure claims was 85.2% (95% CI 80.2, 90.2). Of the 29 patients found to be having a flare; 2 were inpatient, 7 were seen in the Emergency Department, and 20 were seen in an outpatient clinic.

DISCUSSION

We developed claims-based algorithms for gout flares using a combination of diagnosis codes, medication claims and procedure codes and validated the algorithms through our EMR. Our study demonstrated a marginal ability of claims-based algorithms to correctly identify gout flares, with the PPV for gout related medications ranging from 50–54%. Our secondary analysis limiting the algorithm to outpatient encounters only increased the PPV slightly to 56%. The same-day procedure and diagnostic codes resulted in the strongest PPV of 68.4%, which could be expected as joint aspiration and intra-articular glucocorticoids are more specific to gout management then oral anti-inflammatory agents. These findings suggest that the utility and accuracy of claims-based algorithms is likely limited in studies assessing the effectiveness of gout treatment on flares. In contrast, the NPV of the flare algorithm combined both medication and procedure claims was high at 85%. In other words, 85% of the patients who were identified as not having gout flares by the algorithm had no

gout flares on the index date in their medical record. Of the 29 patients that were identified as having no flare by the algorithm but had acute flare documented in EMR, 2 were inpatient admissions. This is one of the limitations in our algorithms as Medicare claims do not have information on in-hospital use of medications. The high NPV raises the possibility that a claims-based algorithm for absence of gout flare is well suited to identify a cohort of gout patients with a low probability of having had a flare. Future studies for medications or interventions aimed at preventing gout flares could make use of such an algorithm that accurately identifies patients without subsequent flares.

There is a paucity of data on the validity of claims-based algorithms for gout flares, but a few studies have assessed the validity of different definitions of gout flares using the EMR with and without claims data. Rothenbacher *et al.* used The Health Improvement Network database in the UK to obtain visit and treatment information. Gout flares were defined as having a recorded prescription of colchicine or when there was a healthcare visit recording gout together with at least one of the following treatments within 1 week: joint aspiration or injection, prescription of NSAIDs or prescription of corticosteroids or adrenocorticotropic hormone [15]. While the flare algorithm was reportedly validated with manual review of 100 random chart samples, the specific data or PPV were not published, making it difficult to compare with our results [15]. Zheng *et al.* studied the validity of a computer-based method to automatically identify gout flares using natural language processing and machine learning from the EMR compared to a claims-based algorithm [16]. In this study, the claims-based algorithm included ‘a diagnosis code of gout followed within 7 days by use of gout-related medications, joints radiograph or other imaging tests, joint aspiration, synovial fluid test, or serum urate test’ or ‘a diagnosis code for joint pain followed within 7 days by use of colchicine’. The PPV of the natural language processing and machine learning method to identify patients with ≥1 gout flare was 98.5% compared to 95.2% using the claims-based algorithm. In addition to the difference in the components of the algorithm from our algorithms, a few characteristics of their study may explain the high PPV of their claims-based algorithm. First, this study evaluated whether the algorithm correctly identified patients with at least 1 flare at any point during the 15-month study period different from our study, which required the physician documentation of gout flares within 7 days from the claims-based flare date (i.e. index date). Second, this study included patients with gout on urate-lowering therapy and the prevalence of having at least 1 gout flare was nearly 30% [16].

Our study demonstrates a very high PPV for a prevalent diagnosis of gout, 98–99%, in comparison to prior studies[7,8,10]. However, this study did not use American Rheumatism Association 1977 criteria to substantiate the gout diagnoses, but rather based the validation on documentation of gout in the medical record. Secondly we used a cohort of patients pre-selected to have an ICD-9 for gout or hyperuricemia which may explain the high PPV in our cohort.

This study has limitations. While a preliminary definition of gout flares has been published consisting of patient-reported flare, joint pain at rest, warm joints swollen joints, and pain at rest, we did not have access to first hand patient report[17]. We therefore used physician documentation of flare in the assessment portion of the clinical note. Ideally flare diagnosis would be confirmed by characteristic clinical presentation and exam such as put forth in the

American Rheumatism Association 1977 criteria but we were limited by the varying levels of documentation detail in the medical record and therefore defined flare more broadly as physician documentation in the assessment. We would anticipate that use of the criteria as a gold standard would further lower the PPV as it is not standard for physicians to routinely document to the level of detail necessary to meet the criteria. Patients may self-treat gout flares without seeking medical attention and we understand that this may cause an underestimate of gout flares. We assessed only PPVs but not the sensitivity and specificity of the algorithms. As the PPV is related to the baseline prevalence of the disease in a population, the PPVs of our flare algorithms may be an overestimate since they represent an older Medicare population, and gout flares may be more common in older adults than those aged younger than 65. Our results from a single U.S. academic medical center may not be generalizable to the greater population, but, as a large referral center, our patient base is diverse. Though Medicare provides detailed records of outpatient medication use there is no data on inpatient use of medications. While performance of our algorithms may improve if the data source has both inpatient and outpatient medication records, we did not see a significant improvement in the PPV when the encounters were limited to outpatient. Lastly the medication claims were not restricted to new claims and may have reflected ongoing therapy, lowering our PPV.

In conclusion, a claims-based algorithm did not appear to accurately identify gout flares in our Medicare eligible patient population and would have limited utility in comparative effectiveness studies. Our algorithm, however, did demonstrate a strong NPV and could be used to define a subset of well-controlled or managed gout patients with infrequent flares for studies in gout treatment or prevention.

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Key Points

- No claims-based algorithms for gout flares have been validated
- Claims-based algorithms had low PPV for gout flares
- Claims-based algorithms accurately determine the absence of acute flares in patients with gout.

Pharmacoepidemiol Drug Saf. Author manuscript; available in PMC 2017 July 01.

Table 1

Gout-related diagnosis, procedure, J codes and related medications

ICD-9 code	Description	J code	Description	CPT code	Description
274.00	Gouty arthropathy unspecified	1020	methylprednisolone 20mg	20600	Arthrocentesis, aspiration and/or injection of small joint/bursa
274.01	Acute gouty arthropathy	1030	methylprednisolone 40mg	20605	Arthrocentesis, aspiration and/or injection of intermediate joint/bursa
274.02	Chronic gouty arthropathy without mention of tophus	1040	methylprednisolone 80mg	20610	Arthrocentesis, aspiration and/or injection of major joint/bursa
274.03	Chronic gouty arthropathy with tophus	1094	dexamethasone acetate		
274.81	Gouty tophi of ear	1100	dexamethasone sodium		
274.82	Gouty tophi of other sites, except ear	1700	hydrocortisone actetate		
274.89	Gout with other specified manifestations	1710	hydrocortisone sodium phosphate, up to 50mg		
274.90	Gout, unspecified	1720	hydrocortisone sodium succinate		
		2650	prednisolone acetate		
		2920	methylprednisolone sodium succinate, up to 40mg		
		2930	methylprednisolone sodium succinate, up to 125mg		

NSAID	Cox-2 selective inhibitor	Oral glucocorticoid
Ibuprofen	Celecoxib	Cortisone
Diclofenac	Rofecoxib	Hydrocortisone
Naproxen	Valdecoxib	Prednisone
Flurbiprofen		Methylprednisolone
Ketoprofen		Triamcinolone
Ketorolac		Dexamethasone
Sulindac		Bethamethasone
Piroxicam		
Oxaprozin		
Nabumetone		
Mefanamic acid		
Meclofenamate		
Fenoprofen		
Diflunisal		

ICD-9 code	Description	J code	Description	CPT code	Description
Etodolac					
Meloxicam					
Tolmetin					
Indomethacin					

ICD-9=International Classification of Diseases, 9th Revision; CPT= Current Procedural Terminology, NSAID=non-steroidal anti-inflammatory

Table 2

Baseline Characteristics for patients identified by algorithms

Algorithm	n	Age, years (SD)	Female,%	Uric Acid, mg/dl (SD	MSU documented,%
Medication					
ICD-9 + medication claim for any gout related medications *	503	75.4 (±7.7)	39	8.5 (±2.4)	10
ICD-9 + medication claim for Colchicine **	302	76 (±7.8)	39	8.6 (±2.6)	15
ICD-9 + medication claim for NSAID/Cox-2 selective inhibitor	174	74.5 (± 7.0)	39	7.8 (±1.7)	5
ICD-9 + medication claim for oral Glucocorticoids	270	75.4 (±7.7)	36	8.7 (±2.6)	13
Outpatient					
ICD-9 + medication claim for any gout related medications *	75	70.1 (±11.1)	40	7.4 (±2.1)	6
Procedure					
ICD-9 + CPT or J code within 7 days	290	76.3 (±7.6)	32	8.3 (±2.6)	32
ICD-9 + CPT or J code on same day	196	76.1 (±7.6)	31	8.6 (±2.3)	38

SD= Standard Deviation, ICD-9=International Classification of Diseases, 9th Revision; CPT= Current Procedural MSU= Monosodium urate, NSAID= Non steroidal anti-inflammatory drug.

* Gout-related medications include colchicine, NSAIDs, cox-2 selective inhibitor, and glucocorticoids.

** Medication categories are not mutually exclusive.

Table 3

Predictive values of the algorithms

Algorithm	Records Identified	Flare cases		Documentation of gout	
	n	n	PPV% (95% CI)	n	PPV% (95% CI)
Medication					
ICD-9 + medication claim for any gout-related medications *	503	268	53.3 (48.9, 57.7)	498	99.0 (98.1, 99.9))
ICD-9 + medication claim for colchicine	302	163	54.0 (48.4, 59.6)	300	99.3 (98.3, 100)
ICD-9 + medication claim for NSAID/cox-2 selective inhibitor	174	87	50.0 (42.6, 57.4)	173	99.4 (98.3, 100)
ICD-9 + medication claim for glucocorticoids	270	145	53.7 (47.8, 59.7)	266	98.5 (97.0, 100)
Outpatient					
ICD-9 + medication claim for any gout-related medications *	75	42	56.0 (44.8, 67.2)	74	99.0 (96.8, 100))
Procedure					
ICD-9 + CPT or J code within 7 days	290	172	59.3 (53.7, 65.0)	287	99.0 (97.9, 100)
ICD-9 + CPT or J code on same day	196	134	68.4 (61.9, 74.9)	194	99.0 (97.6, 100)
Negative Predictive					
	Records Identified	Flare cases		Documentation of gout	
	n	n	NPV % (95% CI)	n	PPV% (95% CI)
ICD-9 + NO medication claim for any gout-related medications *	200	29	85.2 (80.2, 90.2)	196	98.0 (96.1, 100)

95% CI= 95% confidence interval, ICD-9=International Classification of Diseases, 9th Revision; CPT= Current Procedural Terminology; PPV= Positive Predictive Value.

* gout-related medications include colchicine, NSAIDs, cox-2 selective inhibitor, and glucocorticoids.