Published in final edited form as:
Curr Rheumatol Rep. 2009 April ; 11(2): 154–160.

Quality of Life and Quality of Care for patients with Gout

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Abstract

Acute and chronic gouty arthritis lead to significant pain, activity limitation and disability and impact patient's health-related quality of life (HRQoL). Many effective therapies are available for treatment of gouty arthritis, yet medication errors in treatment of gout are common. One of the main goals of therapy is to lower serum uric acid, which in turn leads to a reduction in frequency of gout flares. Evidence suggests that the quality of care provided to patients with gout may impact their HRQoL. This review summarizes the evidence with regards to quality of care and quality of life in patients with gout.

Keywords

Quality of Life; Quality of care; gout; Health-related quality of Life; HRQoL

Introduction

Gouty arthritis is characterized by acute, intermittent, inflammatory arthritis that evolves over many years to chronic inflammatory polyarthritis. In severe cases, tophaceous urate deposits and inflammatory arthritis can lead to deformity, disability and radiographic destruction. It is estimated that approximately 5 million Americans have gout [1]. A recent study estimated that $27 million are spent annually for care of new acute gout cases in the U.S. [2]. Gout accounted for 1.4 million outpatient visits in the U.S. in 2002 [3]. These data indicate that gout is a significant public health problem in the U.S., and perhaps worldwide. Efficacious treatment options are available for treatment of gout, yet failure to treat gout appropriately is quite evident.

One practical way to measure the effectiveness of these treatments is by examining processes of care using the evidence-based quality indicators i.e. the measures of quality of care received by patients of gout. Other ways include examining objective outcomes such as normalization of serum urate, delay and/or reversal of radiographic joint damage, or patient-reported outcomes such as gout-specific health-related quality of life (HRQoL), pain and function. However, very large samples are needed to examine improvement in outcomes, making this approach difficult for most health care systems, in terms of costs and feasibility. Another limitation of this approach is that these outcome data are not collected frequently as part of regular clinical care in most health care systems. Therefore, quality of care is

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assessed by examining errors in medication use or by assessing compliance with quality of care indicators.

The morbidity of gouty arthritis is mostly related to acute arthritis flares, chronic polyarthritis, tophaceous masses and joint destruction. Thus, arthritis impacts health-related quality of life (HRQoL) of patients with gout. Patients with gouty arthritis also have significant medical comorbidity load, which can also impact their HRQoL. This review focuses on recent advances in these areas of quality of care and quality of life in patients with gout.

Quality of Care for Gout

The Agency for Health Care Research (AHRQ) defines quality of care as "The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge". In the section following, we examine the data regarding errors in medication and laboratory monitoring and non-compliance with evidence-based quality of care indicators for gout [4].

Errors in Medication prescription and Laboratory monitoring

Medications used for treating gouty arthritis can be broadly divided into two categories: (1) Urate-lowering agents- most commonly used is Xanthine oxidase inhibitor, allopurinol followed by uricosurics, probenecid and sulfinpyrazone and benzbromarone (not available in the U.S.); (2) anti-inflammatory medications- Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and colchicine, used for acute flares and for prophylaxis against flares during initiation of urate-lowering agents. Long-term therapy with urate-lowering agents (usually life long) is indicated in patients with gouty arthritis with ≥2 attacks/year, radiographic destruction or tophaceous gout [5,6]. The goal is to reduce frequency of acute flares by achieving target uric acid of ≤6 mg/dl.

The goal of urate-lowering therapy is to decrease serum uric acid to ≤ 6 mg/dl, a cut-off that is supported by published evidence. A recent systematic review examining the optimal target for serum uric acid included 23 studies, of which 4 were randomized controlled trials [7]. Evidence from included studies showed an association of higher serum uric acid with higher risk of gout. Lowering serum uric acid was associated with decreasing gout flare frequency, decreased requirement of non-steroidal anti-inflammatory medications during flares and resolution of tophi. Thus, achieving a target serum uric acid ≤6 mg/dl improves outcomes in gout, and is therefore an important cornerstone of gout treatment.

These studies described errors in medication use and monitoring in all settings-emergency room, in-patient and out-patient.

Chin et al. prospectively studied inappropriate drug use in Emergency Room in 981 patients in Chicago [8]. They found that the most common discharge diagnosis for which MDs added potentially inappropriate drugs were musculoskeletal disorders, back pain, gout and allergy/ urticaria.

Smith et al. performed an audit of 93 patients aged 65 years and above who were prescribed allopurinol at the time of hospital discharge in Australia [9]. The average age was 77 years with 49 men and 44 women. In 47% of patients the allopurinol dose was higher than recommended for the creatinine clearance and in 40% it was lower, indicating that the allopurinol doses were not being adjusted to the creatinine clearances.

Mikuls et al. used the MEDMARX database, an Internet accessible error reporting program designed for use by U.S. hospitals and health care systems, to examine for medication errors in use of gout-related medications. They studied errors in use of allopurinol, colchicine, probenecid and sulfinpyrazone from 1999–2003 [10]. Of the 582,397 medication errors, 891 (0.15%) errors were related to gout-specific medications. The most frequent gout medication errors occurred with allopurinol, 524/891 followed by colchicine, 315/891. The commonest errors in colchicine and allopurinol use included illegible/incomplete orders followed by excessive dosing, many in patients with renal failure. Compared to errors occurring with other treatments, physicians were more commonly implicated in gout medication errors (23–39% vs. 7%, $p<0.0001$) and nurses less often (23–27% vs. 50%).

In contrast to other studies, Ly et al. found a moderately good compliance of gout care with New Zealand Rheumatology Association (NZRA) guidelines[11]. This retrospective chart review in 100 patients who met ACR preliminary criteria for gout included two cohorts, 50 patients who received colchicine for acute gouty arthritis (mean age, 58 years) and 50 patients with renal impairment who were on long-term prophylactic colchicine (mean age, 66 years; creatinine ≥2 mg/dl or creatinine clearance ≤50 ml/min). For treatment of acute gouty arthritis, colchicine was prescribed according to the in 96% (48/50) patients at a total dose of ≤2.5 mg/day. Six-monthly CBC and CK laboratory testing was done in 76% (38/50) on long-term colchicine, in accordance with NZRA guidelines. Laboratory monitoring identified one patient who developed colchicine induced myopathy.

In a retrospective study, Dalbeth et al. examined whether the allopurinol dosing in 227 patients attending rheumatology clinic was adjusted to creatinine clearance [12]. 10% (22) patients were taking lower than recommended allopurinol dose, 161 (71%) recommended dose and 14% (44) higher than recommended doses. Serum uric acid was lower in those receiving higher than recommended allopurinol doses compared to the other two groups, i.e., 38% vs. 19% and 15% reached target uric acid, the differences were significant between higher vs. recommended doses ($p<0.01$).

Singh et al. studied a cohort of veterans with gout, who received a new allopurinol prescription [13]. Quality medication use and monitoring were assessed in the 643 patients using published evidence ranging from randomized controlled trials to pharmacokinetic data. Forty-six percent (297/643) gout patients were prescribed the allopurinol continuously; rest had one or more discontinuations lasing 30 days or longer during follow-up. Only 20% gout patients reached target uric acid below 6 mg/dl, 20% had a uric acid check and did not reach target uric acid and 61% had no serum uric acid check. Colchicine or NSAID prophylaxis was started before or on the day of new allopurinol prescription only in 48% (169/643).

Sarawate et al. analyzed data from a managed care plan with gout with an average age of 57 years, 76% men with Deyo-Charlson Index of 0.9 [14]. In 3,651 patients with newly diagnosed gout who received allopurinol, 87% (2094/2405) discontinued therapy (defined as more than 1.5 times duration between refills compared to the last refill duration). Patients had bimodal distribution for allopurinol use i.e., most had Medication possession ratios (MPRs) of <10% or >90%. In those with newly diagnosed gout taking allopurinol, 83% (892/1077) had no claim for SUA testing within 6-months of allopurinol initiation. Fifty-three percent of the patients with gout and renal impairment (creatinine >2mg/dl or a diagnostic code for renal impairment) received allopurinol dose ≥300 mg/day (higher than the recommended dose).

Roddy et al. studied the adherence to EULAR guidelines for management of chronic gout using two populations from general practice in the UK [15]. Of 4249 patients completing the

questionnaire, 488 reported gout or acute attacks and 164 confirmed to have gout on clinical exam by an expert. Overall, 30% (44/164) patients were taking allopurinol. Of 10 patients with tophaceous gout, 20% were taking allopurinol and 40% (4) had taken allopurinol in the past. 31 (70%) current allopurinol users were taking a dose of 300mg daily. 25% (2/8) took prophylactic colchicine and/or NSAID during initial allopurinol prescription.

Pal et al. studied a clinic-based of 429 patients with a diagnosis of gout or on gout medications from 12 general practices in the UK [16]. The mean age of gout patients was 64.5 with M: F ratio of 4:1. Six percent patients were on NSAIDs more than 2 years after initiation of allopurinol. In most patients, allopurinol was started before the acute gout has resolved. Most patients (61%) had no laboratory test while on medication treatment. A referral to rheumatology department was made in 9%. Counseling on reducing alcohol intake was given to only 42% patients.

In an internet-based study, Neogi et al. examined inappropriate therapy in acute gouty attack and its predictors [17]. 232 had gout based on review of records by the rheumatologist. The mean age was 53 years, 81% were male and median disease duration was four years. Definitely inappropriate therapy was defined as initiation of allopurinol during an acute attack, and possible inappropriate therapy, the use of analgesics, alternative remedies or no medications during acute attack (appropriate therapy defined as use of NSAIDs, colchicine or corticosteroids). 26% received either definitely or possibly inappropriate therapy.

Poor Compliance with Quality of Care Indicators in Gout

Quality of care is frequently measured using various quality indicators (QIs). QIs are process measures of health care quality that make the use of readily available healthcare data. A key feature of QIs is that they have a well-defined numerator and denominator, which can easily extracted from the healthcare data. These are in the IF-THEN_BECAUSE format, for example, "**IF** a patient with tophaceous gout is given an initial prescription for a urate-lowering medication (xanthine oxidase inhibitor, probenecid, or sulfinpyrazone) *and* lacks both 1) significant renal impairment (a serum creatinine level ≥2 mg/dl or measured/ estimated creatinine clearance ≤50 ml/minute) and 2) peptic ulcer disease, **THEN** a prophylactic anti-inflammatory agent (colchicine or NSAID) should be given concomitantly, **BECAUSE** prophylactic anti-inflammatory therapy reduces the risk of rebound gout attacks, which frequently follow the initiation of urate-lowering therapy".

Mikuls et al. examined the UK General practitioner Research Database from 1990–99 and identified 63.105 patients with a code for hyperuricemia or gout [18]. They examined the three QIs regarding use of allopurinol. Physician non-compliance varied 25–57%. 25% (48/145) were non-compliant in lowering of initial allopurinol dose in patients with renal failure, 25% non-compliant in adjusting allopurinol dose adjustment when using azathioprine or 5-mercaptoprine and 57% treated asymptomatic hyperuricemia with allopurinol (non-compliant).

Singh et al. assessed three quality indicators in 663 eligible veterans with gout with an average age of 68 years, 99% men with Charlson Index of 2.5 [19]. Physician non-adherence with quality indicators varied from 24% for serum uric acid check within 6-months of initiating a new allopurinol prescription to 78% for dosing of allopurinol <300 mg/day in presence of creatinine clearance <50 ml/minute or creatinine >2 mg/dl. 35% of patients receiving colchicine for longer than 6-months received a CBC and CK check within 6-months. Overall adherence to all applicable quality indicators was low at 22% (144/663).

These studies highlight that inappropriate treatment of gout is common in various settings. These rates of compliance with quality indicators for gout is similar or lower than those

reported for chronic disease care quality indicators in two U.S. national samples, 56% [20] and 59% [21]. This suggests that gout treatment is an area that needs improvement.

Predictor of Poor Quality Care in patients with Gout

Sarawate et al. examined the predictors of high medication prescription ratio and of receiving a serum urate test after initiation of new allopurinol prescription [14]. Patients with previously diagnosed gout were 3 times more likely than newly diagnosed gout and those with hypertension were 1.4 times more likely than those without to have Medication possession ration (MPR) of 80% or higher for allopurinol (Table 1). On the other hand, patients with gout flare before post-index serum urate testing were half as likely as those without flare to have MPR ≥80%. Factors associated with getting postindex serum urate testing were: renal impairment, odds ratio 3.2, number of medications, 1.53 per medication; baseline SUA level, 1.14 per 1mg/dl uric acid level; colchicine use, 0.55.

Neogi et al. examined the predictors of inappropriate therapy during an acute gout attack [17]. The two significant predictors of inappropriate therapy were consultation with a physician during acute attack, associated with higher odds (95% confidence interval) of 2.5 (1.3, 4.7) and increasing number of gout attacks, associated with lower odds of 0.8 (0.7–0.9).

Singh et al, examined the predictors of overall physician-adherence with 3 quality indicators in their study of 643 veterans with gout [19]. Older age and more inpatient visits per year were associated with lower adherence to quality indicators. Higher number of outpatient visits or greater number of health care providers were associated with higher adherence.

Mikuls et al. in their study of quality indicators in GPRD patients found that male gender, older age, chronic renal failure and a greater number of concomitant medications were significantly associated with inappropriate treatment for symptomatic hyperuricemia [18].

Singh et al examined the predictors of continuous allopurinol, use of colchicine or NSAID prophylaxis and of achieving target serum uric acid in veterans with gout receiving a new allopurinol prescription [13]. Higher number of outpatient visit days, more primary care or rheumatology visits and lower comorbidity were associated with better care patterns.

Thus, multiple factors predict patterns of poor physician compliance and gaps in quality care in patients with gout. Efforts aimed at improving quality of care may choose to focus first on high-risk patients, i.e., older patients, those with higher comorbidity, renal failure and/or receiving more concomitant medications.

What are causes of physician non-compliance with Gout Quality Indicators?

Gout is mostly managed by non-rheumatologists in the U.S. and worldwide. Survey studies of general practitioners have assessed reasons for lack of joint aspiration during acute gouty arthritis, initiation of urate-lowering treatment based on clinical suspicion rather than documentation of urate crystals in joint fluid for urate crystals and of not adhering to published recommendations for gout care in Europe [22,23] and China [24]. To our knowledge, there are no published surveys of general practitioners, family practitioners and/or internists that examine the reasons for physician non-compliance with quality indicators and with appropriate medication use and monitoring in patients with gout.

In an informal discussion with internists after presentation of the data regarding gaps in gout care during medical grand rounds, lack of time in a busy outpatient setting and need for

management of multiple comorbidities (other than gout) were cited as the main reasons for treatment and monitoring errors (unpublished observation). More studies are needed to examine what reasons underlie physician non-compliance, so that interventions can be designed to improve gout care. While we discuss exploring reasons for physician non-compliance, studies are also needed to define patient and health care access factors that may contribute to suboptimal care.

Health-Related Quality of Life (HRQoL)

Roddy et al. used WHOQoL-bref questionnaire to compare HRQoL of patients with gout to controls in a primary care population in the UK [25]. 13,684 were surveyed, and 3082 responded (23%), of whom 137 had gout confirmed on clinical examination and 2848 were controls. The mean age of patients with gout was 63 years, 49% had hypertension, 44% had cardio/cerebro-vascular disease and 50% had musculoskeletal comorbidity. Physical QoL was worse in gout versus non-gout patients, but psychological, social and environmental QoL were similar between gout and non-gout patients. In multivariable-adjusted analyses that adjusted for gender, age, musculoskeletal comorbidity, medical comorbidity and gout status, gout was an independent predictor of physical QoL. In patients with gout, no differences in HRQoL were found by serum uric acid level or allopurinol use.

Singh et al. compared the HRQoL of 1,500 veterans with gout with mean age of 68 years to 38,000 veterans without gout with mean age 61 years [26]. In unadjusted analyses, gout patients had much poorer physical HRQoL, but not mental/emotional HRQoL on Short Form-36 for veterans (SF-36V), a validated outcome measure very similar to SF-36, version 2. Adjusted scores (adjusted for socio-demographic, health care access and comorbidity) for physical and mental/emotional HRQoL were similar in patients with gout and without gout, except slightly lower adjusted bodily pain scores in gout vs. non-gout patients (47.1 vs. 49.7, $p<0.01$). In patients with gout, medical comorbidity predicted lower Scores on both physical and mental component summary (PCS and MCS) scales, whereas arthritic comorbidity predicted a lower PCS, but not lower MCS score.

Thus, these two studies had somewhat different findings with regards to association of gout with physical HRQoL, after adjustment for medical comorbidity among other factors. The two studies differed in HRQoL assessments (SF-36V vs. WHO-QoL-Bref), type of medical comorbidities adjusted for, socio-demographics (98% men, mean age of 68 years vs. 81% men, mean age of 64 years), setting (U.S. population-based survey vs. two general practices in the UK), assessment of comorbidity (ICD-9 codes vs. self-report) and response rates (58% vs. 23%). Longitudinal studies with well-defined cohorts of gout and controls are needed to examine the correlates of HRQoL in patients with gout. Recent development of a gout-specific QoL instrument may also help in measuring disease-specific vs. generic HRQoL in patients with gout [27].

Khanna et al. studied 80 gout patients with a mean age of 60 years, 90% men from tertiary care and VA medical center [28]. The SF-36 PCS scores were 38.9 and MCS score 48.6; median HAD-DI was 0.3. Health utilities, as assessed by SF-6D and EQ-5D were 0.68 (range, 0.29 to 1.0) and 0.73 (range, 0.11 to 1.0), respectively.

Is there a link between suboptimal care and poorer HRQoL?

In a previously described study of 868 ER patients, HRQoL of patients was queried using the Short-Form 36 (SF-36) 3-months after the ER visit [8]. Prescription of potentially inappropriate drug in the ER was associated with significantly worse score on SF-36 physical function and pain subscales at 3-month follow-up, 11-points and 13-points lower, respectively [8].

Conclusions

Patients with gout have a reduction in physical HRQoL. Several studies in multiple settings confirm the deficits in quality care for gout, including failure to achieve target uric acid of 6 mg/dl. Many factors including patient age, comorbidity, type of provider seen and health care utilization patterns, predict these inappropriate care patterns. A concerted effort is needed to improve the quality of care and quality of life in patients with gout. This approach may include physician education, patient education and other interventions that can help to prevent errors in use of gout medications. Interventions targeting quality of care have the potential to not only improve standard of care, but also improve the HRQoL in patients with gout.

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Curr Rheumatol Rep. Author manuscript; available in PMC 2013 December 07.

Table 1

Summary of studies of predictors of Quality of Care in patients with gout

Study	Outcome	Potential Predictors	Significant Predictors	Odds/risk ratio (95% CI)	p-value
Sarawate et al. 2006 [14]	MPR ≥80% for allopurinol (n=2,318)	age, sex, pre-index comorbidities, newly or previously diagnosed gout, and gout flare before postindex serum urate testing	Previously diagnosed gout	2.95 (2.45, 3.55)	Not provided
			Hypertension	1.44 (1.20, 1.73)	Not provided
			Gout Flare before post- index serum urate test	0.50 (0.40, 0.63).	Not provided
	Getting Serum urate test after initiation of allopurinol (n=337)	age, sex, pre-index comorbidities, all postindex concomitant medications, gout- specific drugs, and mean baseline serum urate level	Baseline Renal Impairment	3.20 (1.25, 8.23)	Not provided
			Increasing number of medications (per medication increase)	1.53 (1.21, 1.94)	Not provided
			Increasing baseline serum urate level (per mg/dl increase)	1.14 (1.02,1.29).	Not provided
			Colchicine use	0.55 (0.35, 0.89)	Not provided
Neogi et al. 2006 [17]	Definitely or possibly inappropriate drug therapy during acute gouty arthritis (n=202)	age, sex, race, highest education level attained, self- reported comorbidities, body mass index, duration of gout, consulting a physician for the attack, and the total number of recurrent attacks during the study	Increasing number of gout attacks (risk per one attack increase)	0.8 (0.7, 0.9)	0.01
			Consultation with physician during acute attack	2.5 (1.3, 4.7)	0.006
Mikuls et al. 2006 [18]	Inappropriate treatment of asymptomatic hyperuricemia with allopurinol	Age, gender, comorbidity, concomitant medication use, follow-up duration	Age	1.01 (1.00, 1.03)	Not provided
			Male sex	1.82 (1.10, 2.99)	Not provided
			Chronic renal failure	4.89 (1.58, 15.11)	Not provided
			Diuretic use	0.46 (0.27, 0.77)	Not provided
			Total medications	1.25 (1.12, 1.40)	Not provided
Singh et al. 2007 [19]	Overall physician- adherence with 3 quality indicators - allopurinol dose <300 mg in gout patients with renal insufficiency, uric acid check within 6 months of starting a new allopurinol prescription, and _ complete blood count and creatine kinase check every 6 months for gout	race; age; inpatient stays per year; inpatient stays per year with gout as the primary diagnosis; primary care, rheumatology, and other outpatient visits per year; percent service connection and Charlson Comorbidity	Age	0.78 (0.64, 0.96)	0.0207

Study	Outcome	Potential Predictors	Significant Predictors	Odds/risk ratio (95% CI)	p-value
	patients receiving prolonged colchicine therapy (n=643)	Index; and number of health care providers.			
			Non-White Race	1.41 (0.52, 3.84)	0.0353
			Inpatient stays/year with gout as primary diagnosis	0.71 (0.52, 0.97)	0.0151
			Inpatient stays/year	0.57 (0.40, 0.81)	0.0006
			Primary care visits/year	1.28 (1.02, 1.62)	0.0367
			Number of health care providers	1.69 (1.32, 2.15)	0.0001
Singh et al. 2009, in press [13]	Allopurinol discontinuations (n=643)	age, race, inpatient admissions/year, inpatient admissions/year with gout as primary diagnosis, days/year with outpatient primary care visits, rheumatology outpatient visits/year, percent service connection, means test and Charlson Index	Visits per year to Rheumatology or Primary Care		
	Colchicine prophylaxis with new allopurinol prescriptions (n=643)	Same variables as above	Days/year with any outpatient visits	2.08 (1.54, 2.80)	< 0.0001
			Most frequent clinic	a	0.0006
	Getting Serum urate test within 6-months after initiation of allopurinol (n=643)	Same variables as above	Days/year with any outpatient visits	1.60 (1.15, 2.22)	0.0034
			Charlson Comorbidity Index	0.61 (0.44, 0.83)	0.0012

[a]Odds ratio (95% CI) compared to rheumatology: primary care 0.16 (0.07,0.36); specialty medicine 0.12 (0.02,0.58); surgery 0.12 (0.01, 1.22); other 0.13 (0.03,0.53). Each of these has $P < 0.05$ except surgery vs. rheumatology