the remainder of the trial. Blood levels of AZA metabolites 6-thioguanine and 6-methylmercaptopurine were measured biweekly. After receiving 2 weeks of AZA, patients were started on pegloticase (8mg IV) and were treated biweekly for 24 weeks. The primary endpoint was the persistent lowering of serum urate to <6mg/dL at the last three consecutive study visits. Patients who had an increase in serum urate to >6mg/dL while on therapy did not receive additional pegloticase. All patients received infusion prophylaxis with hydrocortisone as well as gout flare prophylaxis.

Results: To date, 12 patients have been enrolled. All patients were male, 75% white and 25% African American. Mean age was 62.4 ± 14.7 years, the mean BMI was 31.1 ± 4.5 and the mean duration of gout was 13.8 ± 9.2 years. At baseline, all patients had visible tophi; 58.3% suffered from gout flares; 81.8% had hypertension; 45.5% had dyslipidemia and 9.0% had coronary artery disease. Of the 12 patients, 6 have completed the full course of treatment with persistent urate lowering and 2 remain on treatment also with persistent urate lowering (figure). 2 patients lost the urate lowering effect, both after 2 doses of pegloticase, and did not receive additional therapy. 1 patient experienced an infusion reaction during the first dose (1 infusion reaction in 90 infusions [1.1%] in the entire trial to date) and 1 subject had subjective symptoms of AZA intolerance with no laboratory abnormalities; these subjects discontinued the study and were not evaluable for the endpoint. No adverse events related to AZA were reported and gout flares were noted in 6 subjects (mean 1.5 flares/patient with flares).

Conclusion: AZA can be used safely in subjects with chronic refractory gout and appears to increase the frequency of subjects experiencing long term lowering of serum urate.

References:

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THU0411

STRUCTURED CARDIOVASCULAR ASSESSMENT INCLUDING CAROTID ULTRASOUND IN GOUT: ANALYSIS OF SUBSEQUENT EVENTS IN THE FOLLOW UP

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Background: Gout is an independent cardiovascular (CV) risk factor. This excess of morbidity and mortality requires optimal management, especially in high-risk individuals. So, the inclusion of subclinical atherosclerosis screening by carotid ultrasound in the initial evaluation may help to accurately stratify the CV risk. However, longitudinal outcomes using this technique are not available in gout.

Objectives: To analyze the new CV events occurred in patients with gout after structured CV assessment incorporating carotid ultrasound.

Methods: Retrospective analysis of an inception cohort of new patients with crystal-proven gout. At baseline, a structured CV assessment was performed considering age, gender, traditional risk factors, CV and renal disease, laboratory data, SCORE and Framingham risk tools and carotid ultrasound; according to 2013 ESC guidelines, CV risk was stratified as low, moderate, high or very high. The cohort includes 356 patients, mean aged 64 years (SD 14.0) mostly males (86.0%), 21.8% with tophaceous gout and mean serum urate at diagnosis of 8.2mg/dL (SD 1.8). The CV risk stratification was: low in 20 (5.6%), moderate in 47 (13.2%), high in 34 (9.6%), and very high risk in 242 (68.0%). Major CV events (coronary disease (CD), heart failure (HF), stroke, peripheral artery disease (PAD) and CV death) were recorded during the follow-up by electronic case reports review. A binary composite endpoint of "new major CV event" was used. The incidence after inclusion in the cohort was estimated. To evaluate potential baseline predictors (clinical and gout-related) of CV events, a Cox regression model was built.

Results: Mean follow-up in the cohort was 41.5 months (SD 16.8). Forty new major CV events have been identified (incidence 3.25%/patient-year), distributed as follows: HF 1.46 (n=18), CV death 0.65 (n=8), CD 0.49 (n=6), stroke 0.33 (n=4), and PAD 0.33%/patient-year (n=4). Per risk stratification, the incidence of a new event was 0.16%/patient-year in the high-risk group and 3.01%/patient-year in the very high-risk, while no events occurred in low and moderate groups. The table shows the univariate and multivariate analysis of baseline variables. An independent association and a trend towards significance were noted for age and to be classified at a very high CV risk at baseline, respectively.

	Univariate regression		Multivariate regression	
	HR (95%CI)	P	HR (95%CI)	P
Age	1.07 (1.04-1.11)	<0.001	1.04 (1.00-1.08)	0.031
Female gender	3.27 (1.68-6.33)	<0.001	1.24 (0.55-2.81)	0.605
Body mass index	1.00 (0.94-1.06)	0.863	-	-
Glomerular filtration rate	0.98 (0.97-0.99)	<0.001	1.00 (0.99-1.01)	0.766
Very high CV risk at baseline	9.54 (2.30-39.64)	0.002	4.11 (0.89-19.02)	0.070
Serum urate at diagnosis	1.19 (1.00-1.42)	0.052	1.12 (0.94-1.33)	0.227
ULT at diagnosis	0.81 (0.29-2.27)	0.688	-	-
Tophi	1.33 (0.66-2.66)	0.422	-	-
Years since first flare	1.00 (0.97-1.03)	0.772	-	-
Number of flares suffered	0.99 (0.97-1.00)	0.255	-	-
Number of involved joints	1.00 (0.89-1.12)	0.976	-	-
Joint pattern at presentation				
-Monoarticular	1.00(ref)	-	1.00(ref)	-
-Oligoarticular	1.86 (0.91-3.80)	0.089	1.35 (0.65-2.82)	0.421
-Polyarticular	2.75 (1.05-7.22)	0.039	1.34 (0.48-3.76)	0.579

HR: Hazard ratio; 95%CI: 95% confidence interval.

Conclusion: First longitudinal study assessing the use of subclinical atherosclerosis screening as part of CV risk assessment in new patients with gout. Those classified at the very high-risk group presented the majority of events, being HF the most frequent. Age, and likely to be classified as very high risk, independently predicted a new CV event during follow-up, data that may be of interest in terms of management of the patient with gout at the time of diagnosis.

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THU0412

EFFECT OF METFORMIN ON CLINICAL GOUT OUTCOMES IN GOUT PATIENTS WITH DIABETES MELLITUS

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Background: Gout and diabetes mellitus type 2 (DM) are frequently co-existing. Metformin is the first choice of treatment for patients with DM type 2, and might – based on previous studies – have beneficial clinical effects on gout through a putative anti-inflammatory as well as serum uric acid (SUA) lowering effect.^{1,2,3}

Objectives: To investigate the anti-inflammatory and SUA lowering effect of metformin in patients with gout starting uric acid lowering treatment (ULT).