

including low immunogenicity allowing continued dosing, lower reported flare rates and convenient monthly dosing.

**Disclosure of Interests:** Stephen Smolinski Shareholder of: Selecta Biosciences, Inc., Employee of: Selecta Biosciences, Inc., Alan Kivitz Shareholder of: Novartis, Consultant for: Abbvie, Janssen, Pfizer, UCB, Genzyme, Sanofi, Regeneron, Boehringer Ingelheim, Sun Pharma Advanced Research, Flexion., Paid instructor for: Celgene, Horizon, Merck, Novartis, Pfizer, Genzyme, Sanofi, Regeneron, Speakers bureau: Celgene, Horizon, Merck and Genetech, Flexion, Wesley DeHaan Shareholder of: Selecta Biosciences, Inc., Employee of: Selecta Biosciences, Inc., Lloyd Johnston Shareholder of: Selecta Biosciences, Inc., Employee of: Selecta Biosciences, Inc., Rehan Azeem Shareholder of: Selecta Biosciences, Inc., Employee of: Selecta Biosciences, Inc., Kei Kishimoto Shareholder of: Selecta Biosciences, Inc., Employee of: Selecta Biosciences, Inc.  
**DOI:** 10.1136/annrheumdis-2019-eular.7769

**SAT0403 SEX DIFFERENCES ARE PRESENT IN CLINICAL CHARACTERISTICS, BUT NOT IN RESPONSE TO DIFFERENT URATE LOWERING THERAPIES IN PATIENTS WITH GOUT**

Sophie Wanten<sup>1</sup>, Minke Ter Stal<sup>1</sup>, Wing-Yee Kwok<sup>2</sup>, Frank van den Hoogen<sup>1,3</sup>, Marcel Flendrie<sup>1</sup>, Noortje van Herwaarden<sup>1,3</sup>. <sup>1</sup>Sint Maartenskliniek, Department of Rheumatology, Nijmegen, Netherlands; <sup>2</sup>Rijnstate ziekenhuis, Department of Rheumatology, Arnhem, Netherlands; <sup>3</sup>RadboudUMC, Department of Rheumatology, Nijmegen, Netherlands

**Background:** Clinical characteristics of gout differ between women and men<sup>1</sup>. Little however is known about the association between these differences and response to treatment. As women seem to have lower mean uric acid excretion compared to men<sup>2,3</sup>, response to uricosuric agents might be better compared to xanthine oxidase inhibitors.

**Objectives:** To identify sex differences in clinical characteristics and response to urate lowering therapy (ULT) in patients with gout and in women difference in response to allopurinol or benzbromarone.

**Methods:** Patients with clinical diagnosis of gout, a first outpatient visit between January 2010 and March 2018 and a follow-up of at least 6 months were included in a retrospective cohort study, with ongoing recruitment, conducted in two rheumatology centres in the Netherlands. From this cohort, patients who started ULT were selected. Clinical characteristics and treatment outcomes of allopurinol and benzbromarone were compared between women and men, including drug survival (corrected for age and renal function) and cumulative incidence of achieving target serum uric acid (<0.36 mmol/l). In women, difference in cumulative incidence of achieving target serum uric acid while using allopurinol or benzbromarone was compared.

**Results:** From a total of 519 (105 women/414 men) patients, 513 (104 women/409 men) and 74 (18 women/56 men) patients were included in the allopurinol and/or benzbromarone group, respectively. Clinical characteristics are described in Table 1. Drug survival was similar for women and men for allopurinol (hazard ratio 1.08; 95% confidence interval (CI) 0.71-1.64) as well as for benzbromarone (hazard ratio 0.66; 95% CI 0.26-1.66) (Figure 1a and b). Cumulative incidences of achieving target serum uric acid were 66% (69/104) and 73% (300/409) after allopurinol and 83% (15/18) and 82% (46/56) after

**Table 1.** Clinical characteristics

	Women (n =105)	Men (n = 414)	p-value*
Age (years), median (IQR)	73.9 (54.3-71.6)	62.9 (54.3-71.6)	<0.01
Current alcohol use, n (%)	34 (45)	275 (79)	<0.01
Comorbidities, n (%)	71 (68)	200 (48)	<0.01
Hypertension	41 (39)	76 (18)	<0.01
Renal impairment	36 (34)	80 (19)	<0.01
Diabetes mellitus			
Diuretics use, n (%)	67 (64)	137 (33)	<0.01
Joint involvement, n (%)	14 (13)	68 (17)	0.38
Monoarthritis	64 (62)	220 (62)	
Oligoarthritis	26 (25)	120 (29)	
Polyarthritis			
History or presence of tophi, n (%)	39 (37)	94 (23)	<0.01
Crystal proven gout, n (%)	89 (85)	348 (89)	0.86
Baseline serum uric acid (mmol/L), mean (SD)	0.44 (0.13) (n=93)	0.43 (0.12) (n=360)	0.73

IQR = inter quartile range

\* P-values for categorical variables were calculated by chi-square analysis, for continuous variables the appropriate (non)parametric analysis was used based on Gaussian distribution.

benzbromarone for women and men, respectively. Comparison in women between response to allopurinol and benzbromarone was not statistically significant (p = 0.15).

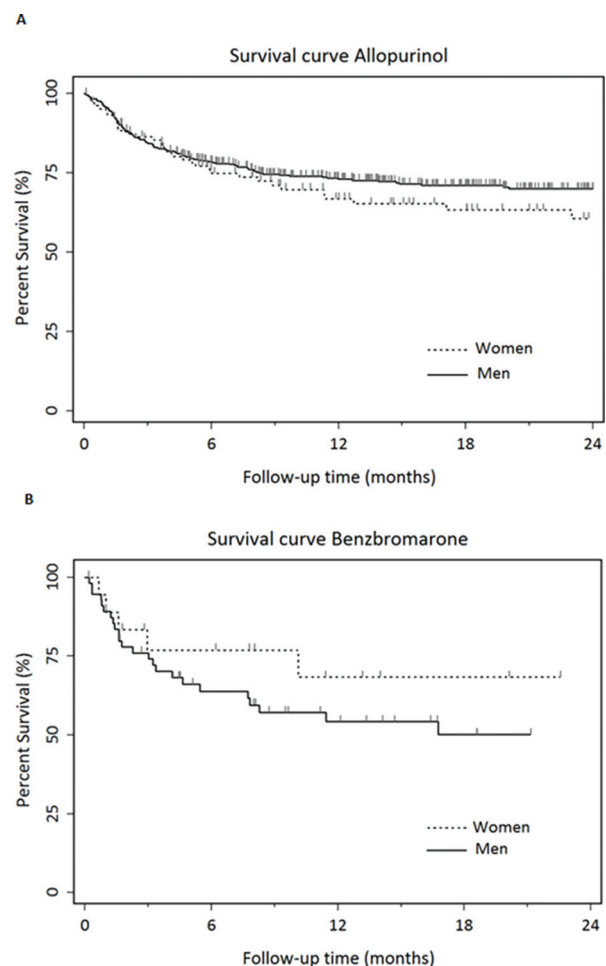
**Conclusion:** Clinical characteristics of gout differ between women and men, confirming previous studies, with women being older, having more comorbidities and using diuretics more often.

Although women have shown to be more uric acid under secretors compared to men, this does not seem to result in a difference in response to a xanthine oxidase inhibitor or an uricosuric agent.

**REFERENCES**

- [1] Harrold LR, et al. Ann Rheum Dis. 2006 Oct;65(10):1368-72.
- [2] Park YB, et al. Clin Rheumatol 2000;19(2):142-6.
- [3] te Kampe R. et al. Ann Rheum Dis.2018;77: Suppl A1637

**Disclosure of Interests:** Sophie Wanten: None declared, Minke ter Stal: None declared, Wing-Yee Kwok: None declared, Frank van den Hoogen: None declared, Marcel Flendrie Grant/research support from: Research grants from Grünenthal, Menarini, Consultant for: Yes, advisory board for Grünenthal in 2017, Paid instructor for: Yes, for Menarini, Noortje van Herwaarden: None declared



**DOI:** 10.1136/annrheumdis-2019-eular.930

**SAT0404 PRETREATMENT AND CO-ADMINISTRATION WITH METHOTREXATE IMPROVED DURABILITY OF PEGLOTICASE RESPONSE: A PROSPECTIVE, OBSERVATIONAL, PROOF-OF-CONCEPT, CASE SERIES**

John Botson<sup>1</sup>, Jeff Peterson<sup>2</sup>. <sup>1</sup>Orthopedic Physicians Alaska, Anchorage, United States of America; <sup>2</sup>Western Washington Arthritis Clinic, Bothell, United States of America

**Background:** Pegloticase is a recombinant DNA-produced porcine-like uricase enzyme, which metabolizes relatively insoluble urate to highly soluble allantoin. It is used in the treatment of refractory gout which has

failed maximal medical management, typically with xanthine oxidase inhibitors (XOI). Studies have shown a complete responder rate of 42% when defined as repeat serum uric acid (sUA) levels <6.0 mg/dL for >80% of the time during months 3 and 6 of treatment. Patients that do not maintain a low uric acid while on pegloticase therapy are presumed to have developed anti-drug antibodies (ADA) which rapidly clear the pegloticase molecule. As is routinely utilized in the treatment of other rheumatologic diseases, coadministration of immunomodulatory medications, such as methotrexate, could potentially temper the development of these ADAs (as defined by maintenance of sUA response) in patients treated with pegloticase for refractory gouty arthropathy.

**Objectives:** The aim of the current case series was to identify and clinically evaluate patients in a real-world practice setting in order to investigate the utility of adding methotrexate to a pegloticase regimen to increase the durability of response.

**Methods:** In this prospective, proof-of-concept, observational case series, 10 sequential patients with refractory tophaceous gouty arthropathy being started on treatment with pegloticase 8 mg every two weeks (as per the label) were identified from 3 separate infusion centers. No inclusion/exclusion criteria were implemented or prescreening performed. Methotrexate (MTX) 15 mg orally once weekly and folic acid 1 mg orally once daily was started one month prior to the initial administration of pegloticase and continued throughout pegloticase treatment. Any infusion pre-medications, which were consistent with standard practices, were administered per the individual physician's discretion as well as management of any gout flares which occurred during the treatment course. As per standard of care, sUA was measured every two weeks, prior to each subsequent infusion. At the completion of pegloticase treatment for all patients, the number and percentage of patients able to maintain an sUA at goal <6.0 mg/dL was recorded.

**Results:** Ten patients ranging in age from 35-80 were identified, from 3 separate infusion centers. There were 143 total pegloticase infusions performed within the observation period. All 10 patients received at least 10 infusions (5 months), 9 patients at least 12 infusions (6 months), 5 patients at least 16 infusions (8 months), 2 patients at least 18 infusions (9 months), and 1 patient received 19 infusions. All 10 patients completed a full course of pegloticase treatment. All patients stayed on MTX 15 mg/week. There were no dose adjustments. 100% of patients were responders as defined by >80% of sUA levels being maintained at goal <6.0 mg/dL during the observation period. None of the 10 patients stopped pegloticase therapy due to increased sUA or loss of response and there were no infusion reactions in any of the 143 infusions or safety concerns identified. Gout flares did occur, primarily following the initial infusion, with less severity/prevalence with subsequent infusions. No patients discontinued treatment because of flares.

**Conclusion:** In this proof-of-concept case series of 10 sequential patients, pretreatment and co-administration of methotrexate 15 mg orally once weekly and folic acid 1 mg orally once daily with pegloticase resulted in a 100% maintenance of pegloticase sUA response with no infusion reactions. Although additional studies would be needed to corroborate these results, these data support a potential paradigm shift in treatment of refractory gout with pegloticase.

## REFERENCE

- [1] Sundy JS, et al. JAMA. 2011;306:711

**Acknowledgement:** Research sponsored by the Alaska Rheumatology Alliance.

**Disclosure of Interests:** John Botson Shareholder of: Publicly traded stock: Horizon, Johnson and Johnson, Pfizer, Rigel, Consultant for: Celgene, Eli Lilly, Genentech, Horizon, Mallinckrodt, Novartis, Pfizer, Speakers bureau: Celgene, Eli Lilly, Horizon, Mallinckrodt, Novartis, Pfizer, Jeff Peterson Consultant for: Celgene, Genentech, Horizon, Lilly, Novartis, Regeneron (2017-2018), Speakers bureau: Abbvie, Horizon, Lilly, Novartis (2017-2018)

DOI: 10.1136/annrheumdis-2019-eular.3475

## SAT0405 GOUT AND HYPERURICEMIA IN THE US: PREVALENCE AND TRENDS

Gurkiral Singh<sup>1</sup>, Bharathi Lingala<sup>2</sup>, Alka Mithal<sup>1</sup>. <sup>1</sup>ICORE, Woodside, United States of America; <sup>2</sup>Stanford, Stanford, United States of America

**Background:** While the prevalence of gout and hyperuricemia is believed to be increasing worldwide, there is little population-based data in the US

after 2008. We evaluated the prevalence of gout and hyperuricemia in the US National Health and Nutrition Examination survey (NHANES) from 2007-08 to 2015-16, and compared these to previously published estimates to study whether the time-trends continue to show an increase in these rates.

**Objectives:** To study the prevalence of gout and hyperuricemia in the US population from 2007-08 to 2015-16.

**Methods:** We studied adults 20 years and older from the National Health and Nutrition Examination Survey (NHANES), beginning with the continuous NHANES 2-year survey cycles from 2007-08 to 2015-2016. The samples in each cycle were selected using a stratified, multistage, clustered probability sampling design. Persons with gout were identified from the home interview question "Has a doctor or other health professional ever told you that you had gout?" Hyperuricemia was defined as a serum urate level of greater than 6.8 mg/dl (supersaturation levels at physiological temperatures and pH), with alternate definitions of greater than 6.0 mg/dl (defined as the treat-to-target level in some treatment guidelines)(1). All statistical analyses were performed with appropriate survey procedures in SAS v9.4 (SAS Institute Inc., Cary, NC). Survey design variables and weight variables were used to account for the complexity of the NHANES survey design with stratification and clustering. Age-adjusted rates were calculated using 2010 US population numbers (direct standardization).

**Results:** In 2015-16, the overall prevalence of gout among US adults was 3.9%, corresponding to a total affected population of 9.2 million US adults. Gout was significantly more prevalent in men (5.2%) compared to women (2.7%), and the prevalence increased with age. Hyperuricemia (above 6.8 mg/dl) was seen in 14.6% of US population (estimated 32.5 million individuals), and was much more common in men (24.7%) compared to women (5.2%). The alternative definition of hyperuricemia (more than 6.0 mg/dl) was seen in 29.9% of individuals (estimated 66.6 million adults). Both hyperuricemia and gout were less prevalent in Mexican-Americans compared to Whites and African-Americans. No significant trends were identified in the age-adjusted prevalence of gout and hyperuricemia. Statistical comparisons between 2007-08 and 2015-16 age-adjusted rates were not significant.

**Conclusion:** While the age-adjusted prevalence of gout and hyperuricemia has remained unchanged in the most recent decade from 2007-08 to 2015-16, the estimated total number of persons with self-reported gout has gone up from 8.3 million to 9.2 million, reflecting the growth and increased aging of the US population. The age-adjusted prevalence of hyperuricemia has declined slightly but the total number of affected individuals is virtually identical (32.5 million in 2015-16 compared to 32.1 million in 2007-08). While the stabilization of gout and hyperuricemia prevalence rates is encouraging, our study highlights the still considerable burden of gout and hyperuricemia in the increasingly aging US population.

## REFERENCE

- [1] Ruoff G, Edwards NL. Overview of Serum Uric Acid Treatment Targets in Gout: Why Less Than 6 mg/dL? Postgraduate medicine. Sep 2016;128(7):706-715.

**Disclosure of Interests:** Gurkiral Singh Shareholder of: Merck, Pfizer, Grant/research support from: Horizon, Acorda, UCB, Consultant for: Horizon, Acorda, Sancilio, Unipharm, Bharathi Lingala: None declared, Alka Mithal: None declared

DOI: 10.1136/annrheumdis-2019-eular.4438

## SAT0406 COMPUTED TOMOGRAPHIC MAPPING OF SPINAL AND VASCULAR URATE DEPOSITION IN THE ABDOMEN WITH CORRELATION TO URIC ACID LEVEL

Juvel Lee<sup>1</sup>, Waleed Abdellatif<sup>2</sup>, Sunghan Jung<sup>1</sup>, Ahmed Negida<sup>3</sup>, Bo Gong<sup>4</sup>, Savvas Nicolaou<sup>5</sup>. <sup>1</sup>Faculty of Medicine, University of British Columbia, Vancouver, Canada; <sup>2</sup>University of British Columbia/Vancouver General Hospital, Radiology, Vancouver, Canada; <sup>3</sup>Faculty of Medicine, Zagazig University, Zagazig, Egypt; <sup>4</sup>Vancouver General Hospital, Vancouver, Canada; <sup>5</sup>University of British Columbia/Vancouver General Hospital, Vancouver, Canada

**Background:** Gout is characterized by accumulation of monosodium urate (MSU) in joints and soft tissues. Gout prevalence is about 1-5% in the western world, predominantly in elderly men. Accurate diagnosis of gout is paramount in managing disease progression and guiding treatment. A meta-analysis in 2018 showed that Dual-Energy CT (DECT) has high sensitivity, specificity and diagnostic accuracy in MSU detection. MSU