the Vascular Endothelial Growth Factor (VEGF) has been advocated to take part to BRONJ pathogenesis via interfering with angiogenesis. No information is currently available on the VEGF concentrations after Zol administration for osteoporosis.

Objectives: To explore change of VEGF concentrations after Zol administration in postmenopausal women with osteoporosis.

Methods: A total of twenty-eight postmenopausal women with osteopenia or osteoporosis and at least one prevalent vertebral fracture were recruited and randomized in two groups. Eighteen women received a single i.v. dose of Zol 5mg, while the other ten served as controls. Serum samples were collected at baseline, after 3 and 30 days, for repeated measurements of VEGF, and measurement of bone turn over markers and 25-hydroxyvitamin D (25(OH)D).

Results: VEGF levels increased significantly after 3 days in women receiving Zol; then levels decreased after 30 days compared with VEGF concentrations at both day-3 and baseline (-18% at day-30 vs. baseline, $p=0.01$). 25(OH)D level, a surrogate of vitamin D status, was associated with VEGF change at the end of the study ($r=0.29$, $p=0.028$), and this association was maintained also after correcting for age, BMI, time since menopause, femoral neck BMD, osteocalcin, C-terminal telopeptide of collagen type 1 and baseline levels of VEGF ($\beta=1.7$, $SE=0.71$, $p=0.03$).

Conclusion: Zol administration induced a reduction of circulating VEGF in postmenopausal women treated for osteoporosis, and vitamin D status has been showed to modulate this change. Further studies in this setting of women are needed to define whether VEGF modifications may predict the risk of BRONJ.

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Crystal diseases, metabolic bone diseases other than osteoporosis

POS1120

PRESENCE OF TOPHI IS ASSOCIATED WITH A RAPID DECLINE IN THE RENAL FUNCTION IN PATIENTS WITH GOUT

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Background: Gout is the most common inflammatory arthritis resulting from a chronic deposition of MSU crystals in the joints and other soft tissues. After the process of repeated tissue damage and repair due to gout, tophi could be formed around the affected joints. Intra-articular tophi may sometimes result in bone destruction, joint deformities, and dysfunction which can adversely affect the patient's quality of life. Furthermore, early-onset tophaceous gout patients are more likely to develop renal dysfunction, however, few studies have investigated if the presence of tophi is related with the progression of renal dysfunction in gout patients.

Objectives: We aimed to compare clinical characteristics of patients with and without tophi at the time of the diagnosis of gout and investigate the effect of tophi on the renal function in gout patients.

Methods: Data of 257 patients who were first diagnosed with gout at the Kangwon National University Hospital from January 2012 to December 2018 were retrospectively studied. Patients were divided into 2 groups according to the presence of tophi at the diagnosis. We compared clinical characteristics and the progression of renal dysfunction between the two groups.

Results: Of all patients, 66 (25.5%) initially presented with tophi. Patients with tophi were older, had a longer duration of symptoms, and had a higher prevalence of multiple joint involvement than those without tophi. The decline in the eGFR was more prominent in patients with tophi than in those without (-4.8 ± 14.5 ml/min/1.73m² vs. -0.7 ± 11.9 ml/min/1.73m², respectively; $P=0.039$). In multivariate logistic regression analysis, a prolonged symptom duration (odds ratio [OR], 1.010; 95% confidence interval [CI], 1.004–1.017; $P=0.001$) and multiple joint involvement (OR, 3.027; 95% CI, 1.831–5.004; $P<0.001$) were significantly associated with increased risk of formation of tophi. The presence of tophi was significantly associated with a rapid decline in the eGFR ($\beta=-0.141$; $P=0.035$).

Conclusion: A prolonged symptom duration and multiple joint involvement were independent risk factors for tophi as the presenting symptom in gout patients. The presence of tophi was associated with a declining renal function. Therefore, an early diagnosis and active treatment are important in tophaceous gout.

REFERENCES:

- [1] Bardin T, Richette P. Definition of hyperuricemia and gouty conditions. *Curr Opin Rheumatol* 2014;26:186-91.
- [2] Liu F, Du GL, Song N, Ma YT, Li XM, Gao XM, et al. Hyperuricemia and its association with adiposity and dyslipidemia in Northwest China: results from

cardiovascular risk survey in Xinjiang (CRS 2008-2012). *Lipids Health Dis* 2020;19:58.

- [3] Dalbeth N, Merriman TR, Stamp LK. Gout. *Lancet* 2016;388:2039-52.
- [4] Ruoff G, Edwards NL. Overview of Serum Uric Acid Treatment Targets in Gout: Why Less Than 6mg/dL? *Postgrad Med* 2016;128:706-15.
- [5] Bieber A, Schlesinger N, Fawaz A, Mader R. Chronic tophaceous gout as the first manifestation of gout in two cases and a review of the literature. *Semin Arthritis Rheum* 2018;47:843-8.

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POS1121

DEMOGRAPHICS, COMORBIDITIES, AND RENAL FUNCTION OF UNCONTROLLED GOUT PATIENTS WHO RECEIVED PEGLOTICASE: FINDING FROM A LARGE US CLAIMS DATABASE

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Background: NHANES data indicate that approximately 9.2 million Americans have gout,¹ with a small subset having uncontrolled disease.² Pegloticase is a PEGylated recombinant uricase enzyme indicated for treating uncontrolled gout that markedly reduces serum uric acid levels (sUA)³ and resolves tophi in treatment responders.⁴ Despite pegloticase availability in the US for many years, real world demographics of pegloticase users in the treatment of uncontrolled gout have not been previously reported in a population-based cohort.

Objectives: This study utilized a large US claims database to examine demographics and co-morbidities of uncontrolled gout patients treated with pegloticase. Kidney function before and after pegloticase treatment and concomitant therapy with immunomodulators were also examined.

Methods: The TriNetX Diamond database includes de-identified data from 4.3 million US patients with gout (as of September 2019), including demographics, medical diagnoses, laboratory values, procedures (e.g. infusions, surgeries), and pharmacy data. Patients who had received ≥ 1 pegloticase infusion were included in these analyses. The number of infusions was evaluated for a subgroup of patients who were in the database ≥ 3 months before and ≥ 2 years after the first pegloticase infusion (i.e. first infusion prior to September 2017) to ensure only complete courses of therapy were captured. In this subpopulation, kidney function before and after pegloticase therapy was examined, along with the presence of immunomodulation prescriptions (methotrexate, mycophenolate mofetil, azathioprine, leflunomide) within 60 days prior to and 14 days after the first pegloticase infusion.

Results: 1494 patients treated with pegloticase were identified. Patients were 63.1 ± 14.0 years of age (range: 23–91), mostly male (82%), and white (76%). Mean sUA prior to pegloticase was 8.7 ± 2.4 mg/dL ($n=50$), indicating uncontrolled gout in the identified population. The most commonly reported comorbidities were chronic kidney disease (CKD, 48%), essential hypertension (71%), type 2 diabetes (39%), and cardiovascular disease (38%), similar to pegloticase pivotal Phase 3 trial populations. In patients with pre-therapy kidney function measures ($n=134$), pre-treatment eGFR averaged 61.2 ± 25.7 ml/min/1.73 m², with 44% having Stage 3-5 CKD. In patients with complete therapy course capture and pre- and post-therapy eGFR measures ($n=48$), kidney function remained stable (change in eGFR: -2.9 ± 18.2 ml/min/1.73 m²) and CKD stage remained the same or improved in 81% of patients. In 791 patients with complete treatment course capture, patients had received 8.7 ± 13.8 infusions (median: 3, IQR: 2-10). Of these, 189 (24%) patients received only 1 pegloticase infusion and 173 (22%) received ≥ 12 infusions. As the data cut-off for this analysis pre-dated emerging data on the use of immunomodulation as co-therapy, only 19 of 791 (2%) patients received immunomodulation co-therapy with pegloticase.

Conclusion: This relatively large group of patients with uncontrolled gout treated with pegloticase had similar patient characteristics of those studied in the phase 3 randomized clinical trials. Patients with uncontrolled gout are significantly burdened with systemic co-morbid diseases. The majority of patients had stable or improved kidney function following pegloticase treatment. As these results reflect patients initiating treatment prior to 2018, before co-treatment with immunomodulation was introduced, this cohort only included a small percentage of patients who were co-treated with an immunomodulator. Future studies using more current datasets are needed to evaluate real world outcomes in patients treated with pegloticase/immunomodulator co-therapy and to evaluate the impact of systemic co-morbid diseases.

REFERENCES:

- [1] Chen-Xu M, et al. *Arthritis Rheumatol* 2019 71:991-999.
- [2] Fels E, Sundry JS. *Curr Opin Rheumatol* 2008;20:198-202.
- [3] Sundry J, et al. *JAMA* 2011;306:711-720.
- [4] Mandell BF, et al. *Arthritis Res Ther* 2018;20:286.