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Conclusion: SFA demonstrated to be an accurate test for the identification of CPP crystals in patients with advanced OA. However, it is not always feasible and carries some risks for the patient. Considering the availability of validated imaging techniques for the detection of CPPD, such as US, SFA could be used in those patients where imaging and clinical data are not definitely confirmatory of the disease.

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PEGLOTICASE/MEHTOTREXATE CO-THERAPY IMPROVED JOIN'T AND PATIENT-REPORTED HEALTH ASSESSMENTS IN PATIENTS WITH UNCONTROLLED GOUT: 12-MONTH EXPLORATORY OUTCOMES OF THE MIRROR OPEN-LABEL TRIAL

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Backround: Gout development follows persistent serum uric acid (sUA) elevation. Patients who are refractory to or cannot tolerate oral urate lowering therapies (ULTs) have limited treatment options. Pegloticase is effective in treating refractory gout, but many patients develop anti-drug antibodies (ADAs), which are associated with loss of urate-lowering efficacy\(^1\,^2\) and infusion reactions (IRs).\(^3\,^4\) In phase 3 trials, the pooled pegloticase responder rate during Months 3 and 6 combined was 42% (8 mg infusion every 2 weeks), with high-titer ADA positive patients losing efficacy prior to 6 months.\(^1\) The 6-month results from the MIRROR open-label trial (79% response rate \([11/14\], 95%CI 49-95%)\(^4\) suggest that methotrexate (MTX) administered in conjunction with pegloticase increases treatment responder rate.

Objectives: To examine longer-term (12-month) exploratory endpoints from the MIRROR open-label trial, including joint, overall health, and gout global assessments. Serial dual-energy computed tomography (DECT) images were also examined when available.

Methods: Adult patients with uncontrolled gout (sUA ≥6 mg/dL with ≥1 of the following: sUA ≥6 mg/dL despite ULT use, intolerance to ULT, or functionally limiting tophaceous deposits) were included. Patients with immunocompromised status, G6PD deficiency, severe renal impairment, or MTX contraindication were excluded. Patients were administered oral MTX (15 mg/week) and folic acid (1 mg/day) 4 weeks prior to and throughout pegloticase therapy (8 mg biweekly infusion for up to 52 weeks). Exploratory outcomes included mean change from baseline (CFB) in number of affected joints (tophi, swollen, tender), Health Assessment Questionnaire (HAQ) scores (Disability Index [DI]; score 0-3), Pain [score 0-100], Health [score 0-100], and Gout Global Assessments (Patient, Physician; score 0-10). A decrease in these measures reflects clinical/patient-reported health improvement. Change in urate deposition volume, as measured on DECT imaging, was also examined as available. Analyses were performed on the modified intent-to-treat (mITT) population (≥1 pegloticase infusions).

Results: 14 patients (all male, mean±SD age: 49.3±8.7 years) made up the mITT population. Mean±SD sUA prior to pegloticase treatment was 9.2±2.5 mg/dL and 13 patients had visible tophi. 3 patients discontinued due to 2 consecutive sUA levels >6 mg/dL and 1 patient completed the study at week 24 (pre-protocol amendment extending treatment from 24 to 52 weeks). 10 patients completed the 52-week study. Of these, 8 patients received 26 infusions and 2 patients received 12 infusions, discontinued pegloticase after meeting their treatment goal at 24 weeks, and started allopurinol while remaining in study under observation. At week 52 (n=10, sUA=1.1±2.5 mg/dL), the number of affected joints improved, along with HAQ measures (Figure 1). Global Assessments of Gout also improved (Physician: CFB=-5.7±2.6, Patient CFB=-4.6±2.1) and majority of subjects had a score of 0 (Figure 1). HAQ Health, HAQ Pain, HAQ DI, and Gout Global Assessments (Patient, Physician; score 0-10) showed a decrease in these measures.

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