Abstract # 1629

Management of Gout with Pegloticase; Real-World Utilization and Outcomes from Trio Health and the American Rheumatology Network (ARN)

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1. Background

Infusion reactions and other adverse events associated with pegloticase may lead to discontinuation of treatment in patient populations that have already failed or are intolerant to other uric acid lowering therapies (ULTs). Maximizing the benefit of pegloticase is critical in the absence of other suitable ULTs. Here, we examine use of pegloticase for patients in US clinical care and identify variables associated with longer time on therapy.

2. Methods

The ARN-TRIO Rheumatology registry contains EMR (fielded and open text), lab, procedure, infusion, medical claims, and specialty pharmacy data generated in care of >75,000 patients by ARN, a network of independent practices with >200 rheumatologists across the US. This study included data for gout-diagnosed patients who initiated their last pegloticase course between Jul 2015 and Oct 2019 with >180 days follow-up from pegloticase initiation (index). A course was defined as pegloticase infusions spaced <90 days apart. Chart reviews were conducted for all study patients to determine treatment status (ongoing vs. discontinued) and documented reasons for discontinuation. To assess consistency of control of sUA <6 mg/dL, evaluations were limited to patients with 2+ sUA measures during treatment. Time to event analyses were by Kaplan-Meier and log-rank or Wilcoxon test.

3. Results

110 of 276 pegloticase-treated patients met study criteria. [TABLE 1] Study population characteristics are provided in TABLE 2. At time of assessment, 86% (95) had discontinued treatment; 16% (18/110) discontinued as intended upon meeting treatment goals and 70% (77/110) had an unplanned discontinuation. [FIGURE 1] The majority of unplanned discontinuations were due to lack of efficacy (37/77, 48%) or adverse events (15/77, 19%). [TABLE 3] Of the 15 patients who discontinued therapy due to adverse events, 80% (12) cited infusion and/or allergic reactions. Median times to discontinuation were 20 weeks overall and 22 weeks for non-planned discontinuation. Controlled sUA (<2 sUA ≥6 mg/dL) and concurrent use of immune-modulating therapies (predominantly methotrexate) were associated with a significantly longer pegloticase duration. [FIGURES 2 & 3] Variables NOT associated with unplanned discontinuation were race, gender, age, payer type, kidney disease, osteoarthritis or osteoporosis, baseline sUA, and pegloticase infusion schedule. None of the 12 patients who discontinued due to infusion or allergic reactions received concurrent immune-modulating therapies.

4. Summary

These observations suggest that treatment with pegloticase may be lengthened with concomitant use of immune-modulating therapies; however, a larger scale prospective study should be done to further elucidate the benefits of immunomodulation beyond durability of treatment, including safety benefits such as minimal to no infusion reactions.

TABLE 1: Patient Selection

Criteria	n
Pegloticase-treated patients in ARN-TRIO Rheumatology registry	276
and had last pegloticase treatment between Jun 2015-Oct 2019	131
and had >180 days follow up as of May 2020	110

TABLE 2: Study Population Characteristics

Patient Demographics – no (%) unless indicated	n=110
Follow up (days) from index- mean (range)	516 (181-1700)
Male	88 (80%)
Age - mean (range)	59.5 (31-85)
<50	26 (24%)
50-64	38 (35%)
65-74	33 (30%)
75+	13 (12%)
Race	
black	15 (14%)
white	54 (49%)
other	1 (1%)
unknown	40 (36%)
Payer	
Commercial	60 (55%)
Medicaid	8 (7%)
Medicare (including dual eligible)	38 (35%)
other	4 (4%)
Disease	
Kidney disease	36 (33%)
baseline sUA ≥6 mg/dL	36/101 (36%)
Concurrent immune-modulating therapies	
methotrexate	25 (23%)
tocilizumab	1 (1%)
rituximab	1 (1%)
apremilast	1 (1%)

FIGURE 1: Patient Disposition as of May 2020

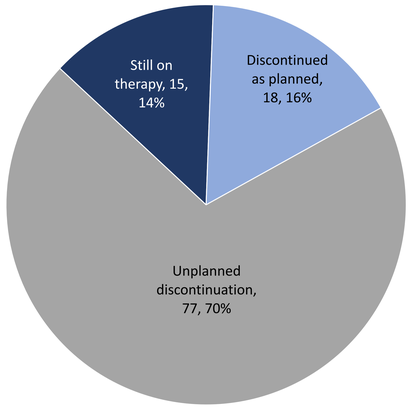
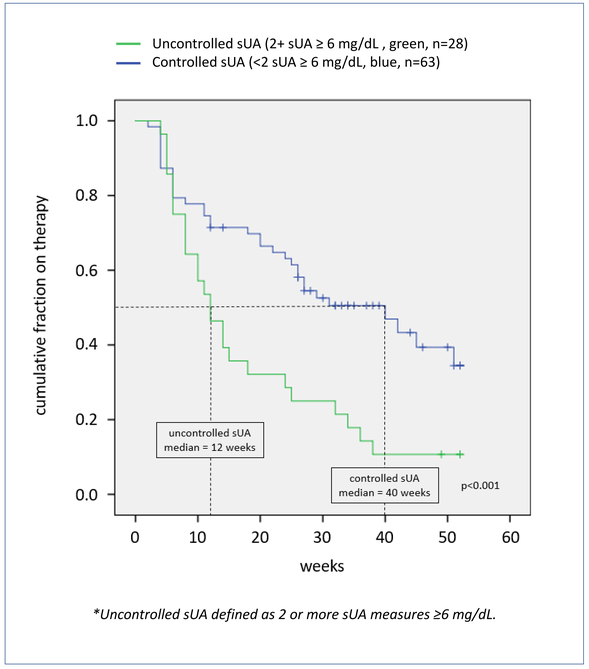


TABLE 3: Reasons for Unplanned Discontinuation (n=77)

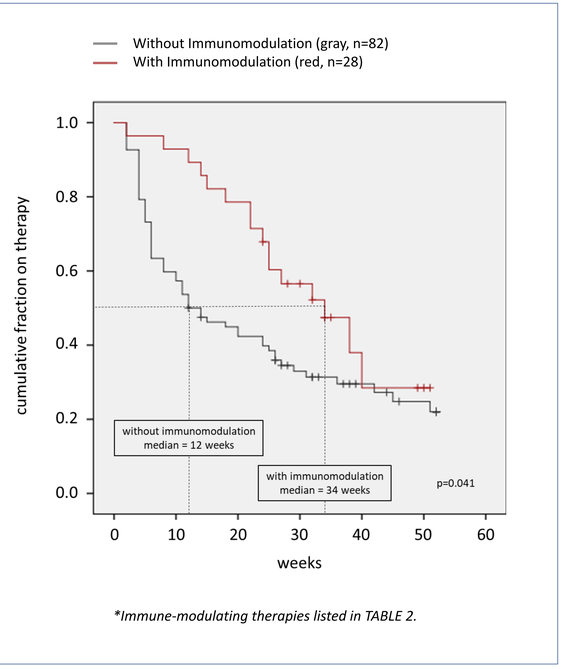
Reasons* obtained from chart review	n (%)
Lack of efficacy	37 (48%)
Adverse events (excludes gout flares or rising sUA)	15 (19%)
Cost	1 (1%)
Health issue unrelated to treatment	2 (3%)
Lost to follow up	8 (10%)
Payer denial	3 (4%)
Unspecified	16 (21%)
Total	77 (100%)
**5 patients have multiple reasons: efficacy & AE (3) or payer denial (1); cost & payer denial (1)*	

FIGURE 2: Time to Discontinuation by Controlled vs. Uncontrolled sUA*



**Uncontrolled sUA defined as 2 or more sUA measures ≥6 mg/dL.*

FIGURE 3: Time to Discontinuation by Presence or Absence of Concurrent Immune-Modulating Therapies*



**Immune-modulating therapies listed in TABLE 2.*

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