Management of Gout after Pegloticase; Observations of US Clinical Practice 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). As such, maximizing the benefit of pegloticase is critical in the absence of other suitable ULTs.

Here, we examine treatment for gout following pegloticase discontinuation for patients in US clinical care.

2. Methods

The ARN TRIO Rheumatology registry contains EMR (fielded and open text), lab, procedure, infusion, and medical claims 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 70 gout-diagnosed patients who initiated their last pegloticase course between Jan 2015 and De 2019 with >90 days follow up from pegloticase discontinuation (index). Statistical analyses included t-test (continuous variables), chi-square or Fischer's exact tests (categorical variables), and Kaplan-Meier and log-ran test (time to event). Assessments of serum uric acid (sUA) were limited to patients with 2+ measures.

3. Results

Study population characteristics are provided in TABLE 1. At ≥90 days past pegloticase discontinuation, 49/70 (70%) initiated a uric acid lowering therapy (ULT). Median time from index to ULT was 13 days; 76% (37/49) occurred within 30 days, 90% (44/49) 90 days, and 96% (47/49) 180 days. [FIGURE 2] Median follow up for patients who did not initiate a subsequent ULT was 404 days, greater than but not significantly different from patients that did initiate ULT post-pegloticase (322 days, p=0.270). The absence of kidney disease was significantly associated with ULT initiation within 180 days (39/47, 83% v. 14/23, 61% non-initiators, p=0.043) [TABLE 1]; variables NOT associated included age, gender, race, ethnicity, payer, CVD, diabetes, non-gout rheumatic diseases, duration of prior pegloticase, and sUA ≥6 mg/dL during pegloticase or at pegloticase discontinuation. Of the 47 patients that initiated subsequent ULT within 180 days, 22 of 47 had 2+ sUA measures during treatment, and 9/22 (41%) had 2+ sUA ≥6 mg/dL. Two or more sUA results post-pegloticase were provided for 6/23 patients that did not initiate ULT within 180 days; 5/6 (83%) had 2+ sUA ≥6 mg/dL. [FIGURE 3]

4. Summary

Consistent sUA <6 ml/dL was not maintained post-pegloticase for half (14/28) of the evaluable patients. As the ACR Guidelines advises the treat to target approach to maintain sUA <6 ml/dL, our results highlight the need for new ULTs and/or better strategies to maximize benefit with available therapies.

FIGURE 1: Treatment Post-Pegloticase (n=70)

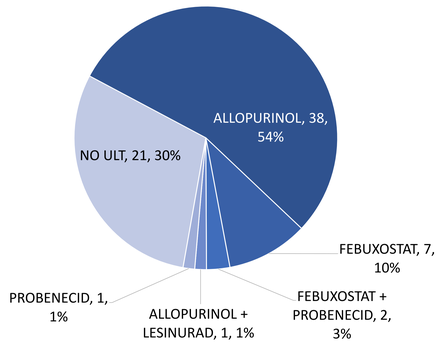


FIGURE 2: Days to Next ULT Post-Pegloticase (n=49)

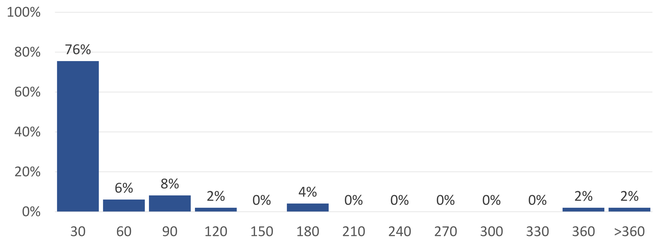
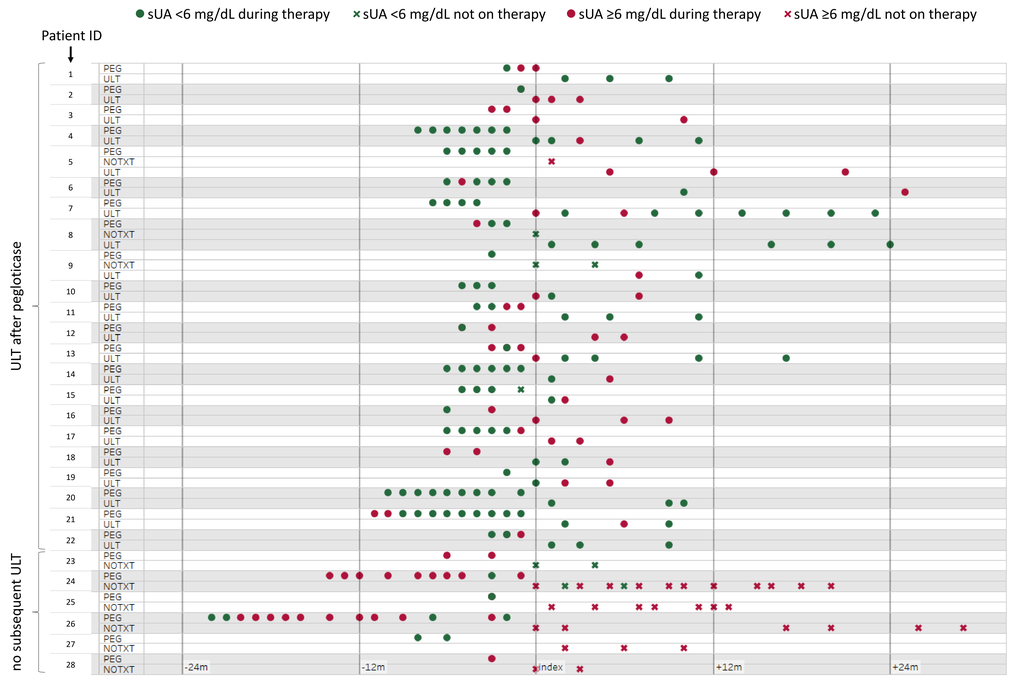


TABLE 1: Study Population Characteristics

Patient Demographics – no (%) unless indicated	No ULT after pegloticase* (n=23)	ULT after pegloticase* (n=47)	Total (n=70)	p
Male	18 (78%)	40 (85%)	58 (83%)	0.475
Age – mean	60	60	60	1.000
Race				0.640
Black	3 (13%)	4 (9%)	7 (10%)	
White	13 (57%)	22 (47%)	35 (50%)	
Other or unknown	7 (30%)	21 (45%)	28 (40%)	
Ethnicity				0.100
Hispanic	0 (0%)	2 (4%)	2 (3%)	
Not Hispanic	12 (52%)	13 (28%)	25 (36%)	
Unknown	11 (48%)	32 (68%)	43 (61%)	
Payer				0.174
Commercial	10 (43%)	26 (55%)	36 (51%)	
Medicaid	2 (9%)	2 (4%)	4 (6%)	
Medicare (including dual eligible)	10 (43%)	16 (34%)	26 (37%)	
Other or unknown	1 (4%)	1 (2%)	2 (3%)	
Disease / Comorbidities				
Osteoarthritis or osteopenia	5 (22%)	6 (13%)	11 (16%)	0.333
Psoriatic arthritis	0 (0%)	2 (4%)	2 (3%)	0.316
Rheumatoid arthritis	4 (17%)	9 (19%)	13 (19%)	0.859
CVD	4 (17%)	6 (13%)	10 (14%)	0.603
Kidney disease	9 (39%)	8 (17%)	17 (24%)	**0.043**
Prior pegloticase treatment				
Duration (days) – mean	244	149	180	0.064
Last sUA ≥6 mg/dL	12/19 (63%)	20/46 (43%)	32/65 (49%)	0.149

*Assigned based on treatment within 180 days of pegloticase termination. 2 patients initiated ULT post pegloticase at or after 360 days and were included in the "No ULT after pegloticase" group for this comparison.

FIGURE 3: sUA During and After Pegloticase (n=28)



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