Management of Gout after Pegloticase; Observations of US Clinical Practice from Trio Health and the American Rheumatology Network (ARN)

Abstract # 1628

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1. BACKGROUND

Pegloticase is approved for severe gout in patients that are intolerant to, or whose disease is ineffectively controlled by, other uric acid lowering therapies (ULTs). The positioning of pegloticase as the last therapeutic option begs the question, how is gout managed once pegloticase is discontinued? Here we examine treatment following pegloticase for patients in US clinical care.

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 Jan 2015 and Dec 2019 with >90 days follow-up from pegloticase discontinuation (index). Comparisons were made using t-test for continuous variables and chisquare or Fischer's exact tests for categorical variables. Time to event analyses were by Kaplan-Meier and log-rank test. To assess consistency of control of sUA <6 mg/dL, evaluations were limited to patients with 2+ sUA measures within the period of interest.



FIGURE 1: TREATMENT POST-PEGLOTICASE (N=70)

FIGURE 2: DAYS TO NEXT ULT POST-PEGLOTICASE (N=49)



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3. RESULTS

70 of 276 pegloticase-treated patients met study criteria; at time of assessment which was \geq 90 days past pegloticase discontinuation, 49/70 (70%) initiated a ULT. [FIGURE 1] Median time from index to ULT initiation was 13 days; 76% (37/49) of initiations 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). After stratification of the study population by ULT initiation within 180 days of pegloticase termination, the only evaluated variable associated with ULT initiation was the absence of kidney disease (39/47, 83% v. 14/23, 61% non-initiators, p=0.043). [TABLE 1] Variables NOT associated with ULT initiation within 180 days post-pegloticase included age, gender, race, ethnicity, payer, CVD, diabetes, non-gout rheumatic diseases, duration of prior pegloticase, and serum uric acid (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 the subsequent ULT with 9/22 (41%) having 2+ sUA \geq 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 \geq 6 mg/dL. [FIGURE 3]

Patient Demographics – no (%) unless indicated	No ULT after pegloticase* (n=23)	ULT after pegloticase* (n=47)	Total (n=70)	р		Patient L	D	sUA <6 mg/dL during therapy	× sUA <6
Male	18 (78%)	40 (85%)	58 (83%)	0.475			PEG ULT		
Age – mean	60	60	60	1.000		2	ULT PEG		
Race				0.640		3	ULT		
Black	3 (13%)	4 (9%)	7 (10%)			4	ULT PEG		
White	13 (57%)	22 (47%)	35 (50%)			5			
Other or unknown	7 (30%)	21 (45%)	28 (40%)			6	ULT		
Ethnicity				0.100		7	ULT PEG		
Hispanic	0 (0%)	2 (4%)	2 (3%)		e S	8	NOTXT ULT		
Not Hispanic	12 (52%)	13 (28%)	25 (36%)		ticas	9	PEG NOTXT		
Unknown	11 (48%)	32 (68%)	43 (61%)		0 පිරි	10	PEG		
Payer	, ,			0.174	r pe		PEG		
Commercial	10 (43%)	26 (55%)	36 (51%)		afte	12	PEG ULT		
Medicaid	2 (9%)	2 (4%)	4 (6%)		ULT	13	ULT		
Medicare (including dual eligible)	10 (43%)	16 (34%)	26 (37%)		_	14	ULT		
Other or unknown	1 (4%)	1 (2%)	2 (3%)			15	ULT PEG		
Disease / Comorbidities	、 <i>,</i>					10	ULT PEG		
Osteoarthritis or osteopenia	5 (22%)	6 (13%)	11 (16%)	0.333		18	PEG		_
Psoriatic arthritis	0 (0%)	2 (4%)	2 (3%)	0.316		19	PEG		_
Rheumatoid arthritis	4 (17%)	9 (19%)	13 (19%)	0.859		20	PEG ULT		••
CVD	4 (17%)	6 (13%)	10 (14%)	0.603		21	PEG ULT		•••
Kidney disease	9 (39%)	8 (17%)	17 (24%)	0.043	L	22	ULT		
Prior pegloticase treatment					UL1	23	NOTXT PEG		
Duration (days) – mean	244	149	180	0.064	lent	24	NOTXT PEG		
Last sUA ≥6 mg/dL	12/19 (63%)	20/46 (43%)	32/65 (49%)	0.149	sequ	26	PEG		• • •
*Assigned based on treatment within 180 days of	pegloticase term	nination. 2 patier	nts initiated ULT p	ost pegloticase	sqns	27	PEG		
at or after 360 days and were included in the "No	ULT after pegloti	case" group for t	his comparison.		0 U	28	PEG NOTXT	-24m	-12m

TABLE 1: STUDY POPULATION CHARACTERISTICS

FIGURE 3: SUA DURING AND AFTER PEGLOTICASE (N=28)



4. SUMMARY

After pegloticase discontinuation, most patients quickly initiated allopurinol. Consistent sUA <6 ml/dL was not maintained post-pegloticase for half (14/28) of the evaluable patients. As the new 2020 ACR Guidelines for the Management of Gout 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.

5 mg/dL not on therapy ● sUA ≥6 mg/dL during therapy × sUA ≥6 mg/dL not on therapy

