

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 chi-square 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.

3. RESULTS

70 of 276 pegloticase-treated patients met study criteria; at time of assessment which was ≥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 ≥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

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.

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

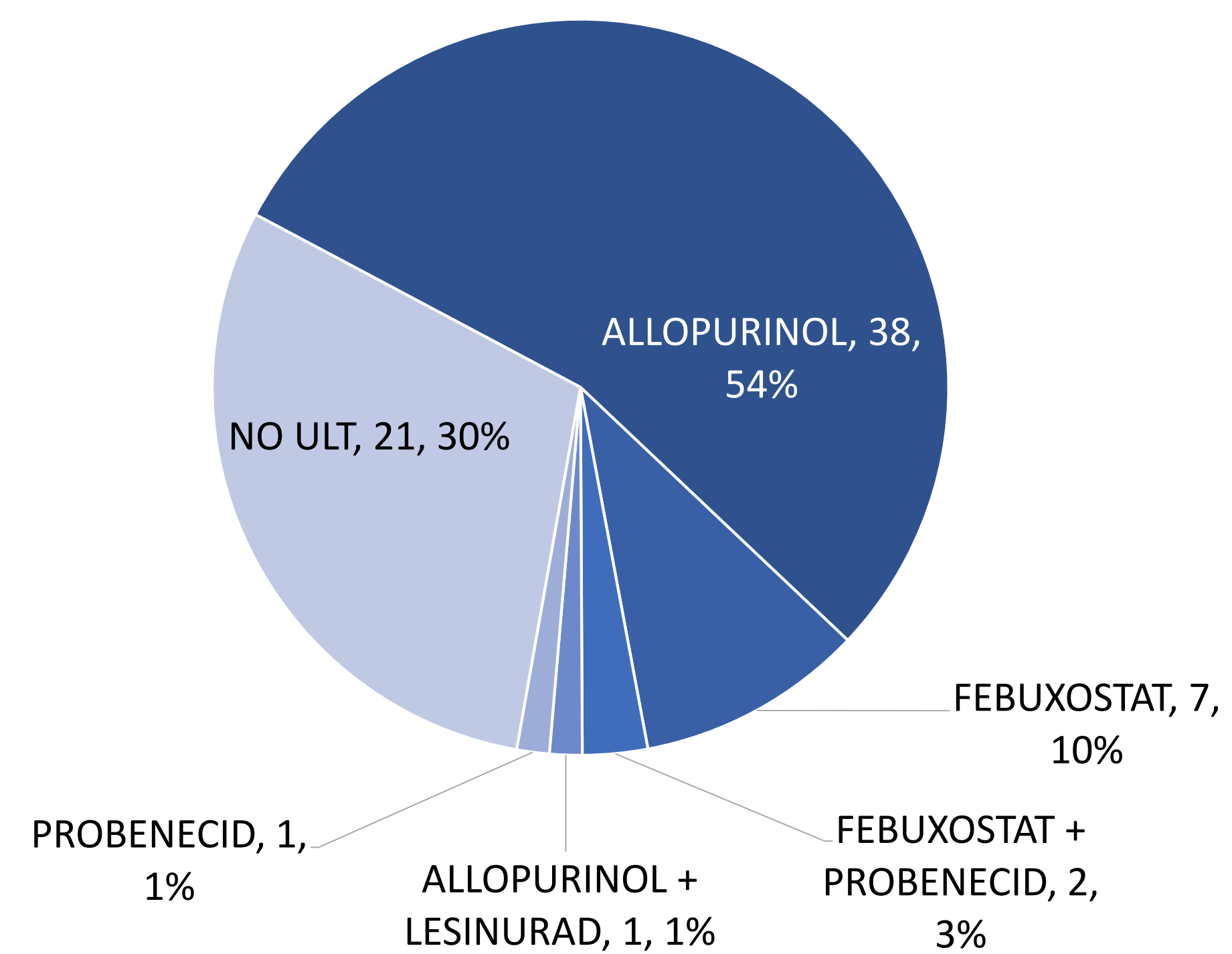


FIGURE 2: DAYS TO NEXT ULT POST-PEGLOTICASE (N=49)

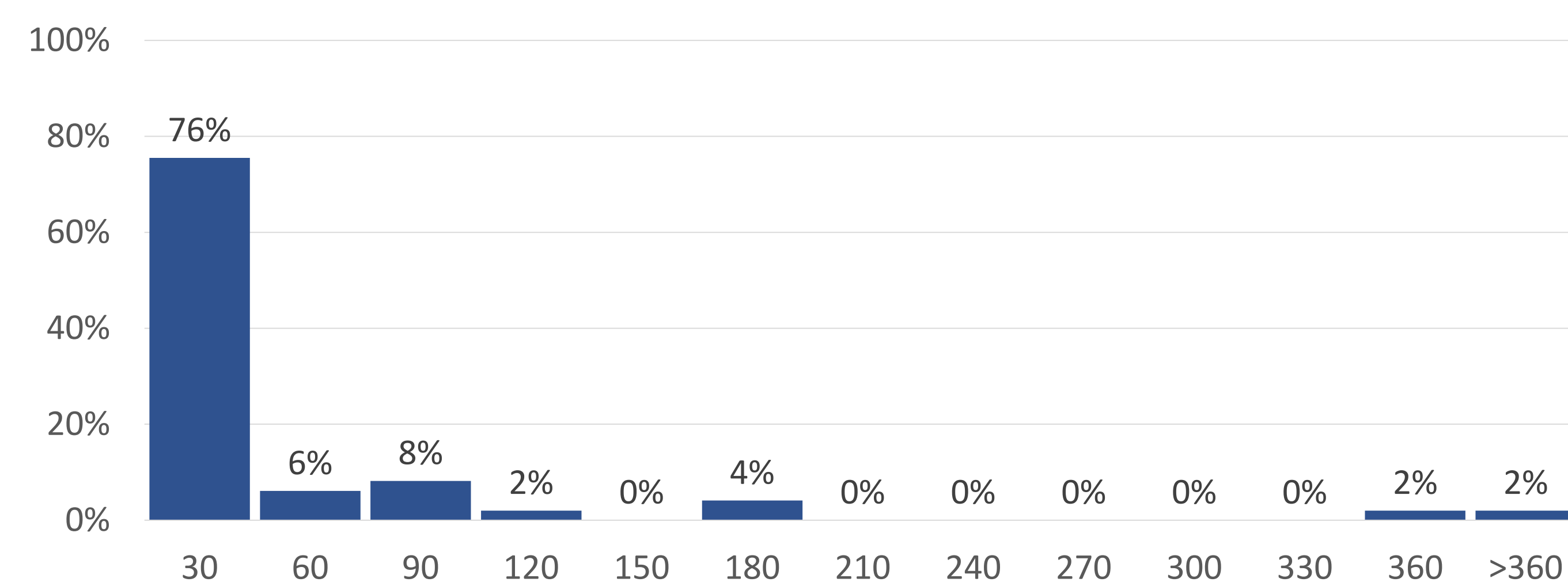


TABLE 1: STUDY POPULATION CHARACTERISTICS

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)

