

LEVOCARNITINE AND VITAMIN B COMPLEX FOR PROPHYLAXIS AGAINST PEGASPARAGINASE TOXICITY IN ADULTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA

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INTRODUCTION

Pegasparginase is an integral part of Adolescent and Young Adult (AYA) acute lymphoblastic leukemia (ALL) treatment protocols.

Adult centers utilizing pediatric inspired protocols have reported higher risk of pegasparginase toxicity including liver damage, pancreatitis, and prolonged cytopenias.

Levocarnitine and vitamin B complex have been used in multiple settings for treatment of pegasparginase toxicity. The combination can also be beneficial as prophylaxis for liver toxicity.

AIM

- Study the safety profile of combination prophylaxis with levocarnitine and vitamin B complex for pegasparginase toxicity in young adults with ALL
- Incidence of grade III or higher hepatobiliary toxicity while on combination prophylaxis
- Incidence of pancreatitis in young adults on combination prophylaxis.

METHOD

A single center, retrospective, descriptive analysis was conducted for adult patients treated with pegasparginase for ALL while on levocarnitine and vitamin B complex for pegasparginase toxicity prophylaxis. Subjects were evaluated for grade 3 or higher liver enzyme elevation, total bilirubin elevation, and amylase/lipase elevation or pancreatitis.

CONCLUSIONS

- These data suggest that levocarnitine and vitamin B complex combination can be safe and effective for hepatobiliary prophylaxis during ALL induction treatment using pegasparginase.
- Reduced toxicity in our patient cohort highlights the potential protective effects of the combination when compared to the historically reported incidence of liver toxicity and pancreatitis of 30-60% and 1-4%, respectively.
- Larger multicenter clinical trials should be considered to confirm these findings.

RESULTS

- *Eighteen patients (age range 18 to 39 years) received levocarnitine and vitamin B complex for prophylaxis while on pegasparginase therapy.*

- *Levocarnitine was given as 990 mg PO TID or QID and vitamin B complex 1 capsule PO daily starting prior to the first dose of pegasparginase and continued through treatment.*

- *No adverse effects of the prophylaxis regimen were reported in medical records.*

- *Of the 18 patients that received pegasparginase, 2 patients (11%) had grade 3 or 4 liver enzyme elevation, defined as >5x ULN or baseline when elevated at presentation, one patient had bilirubin elevation to a maximum of 10.6, and no patients developed pancreatitis.*

- *The subsequent pegasparginase dose was delayed due to toxicity in 4 patients and chemotherapy regimen was changed due to toxicity in 2 patients.*

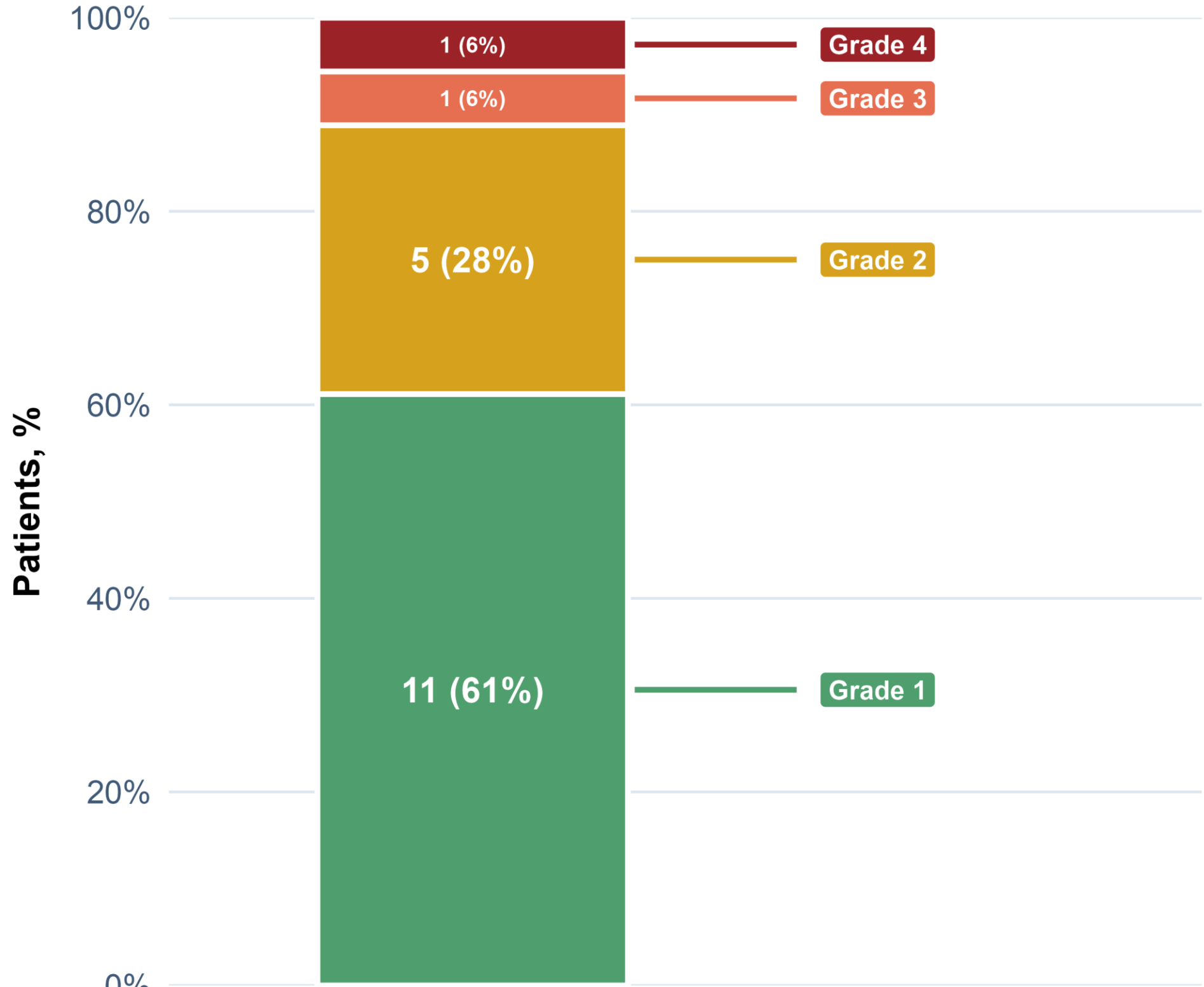
Table 1. Cohort characteristics

Characteristic	Overall, N = 18
Age, years	27 (18–39)
Sex	
Male	9 (50%)
Female	9 (50%)
Induction Regimen	
CALGB 10403	11 (61%)
COG AALL0434	2 (11%)
Other	5 (28%)
Pegaspargase doses, n	2 (1–7)

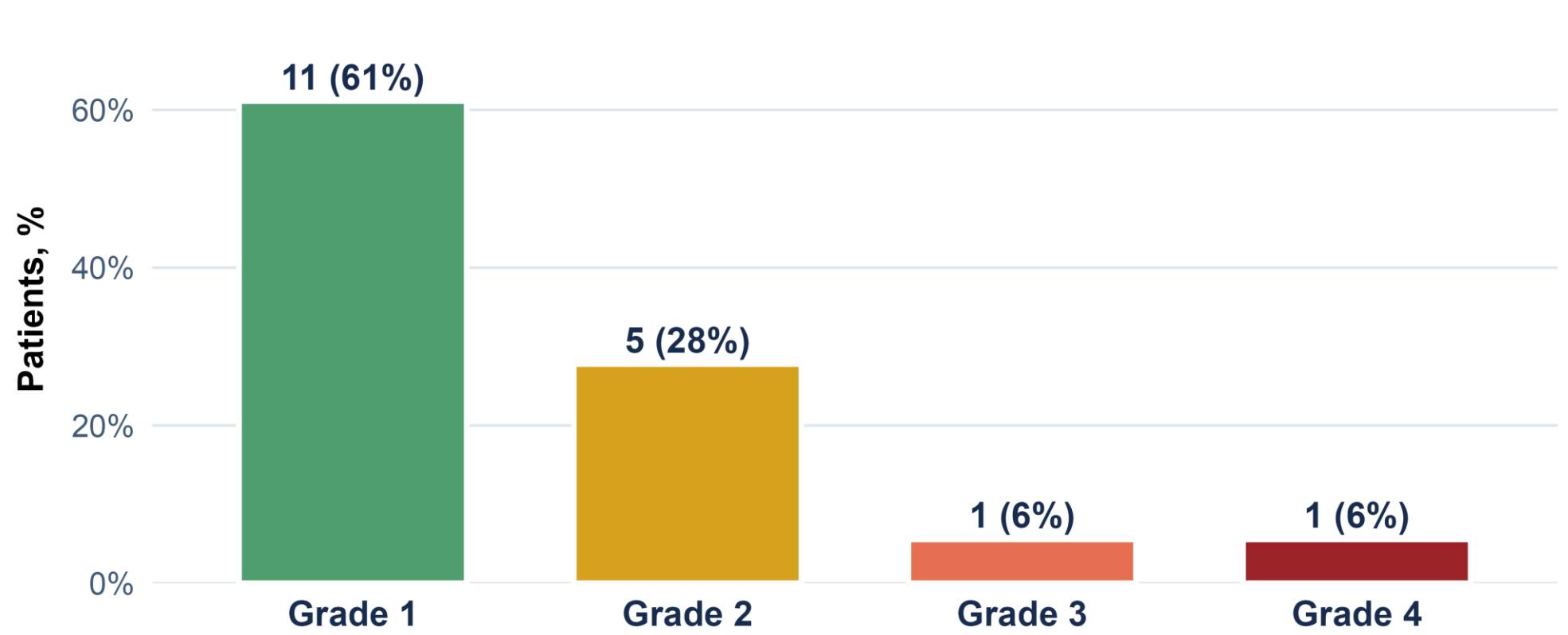
Table 2. Safety and treatment-impact outcomes

Outcome	Observed
Grade 3–4 liver enzyme elevation	2/18 (11%)
Pancreatitis	0/18 (0%)
Pegaspargase dose delayed due to toxicity	4/18 (22%)
Chemotherapy regimen changed due to toxicity	2/18 (11%)
Maximum observed bilirubin	10.6 mg/dL

Maximum grade of liver enzyme elevation within 21 days of pegasparaginase infusion



Maximum grade of liver enzyme elevation within 21 days of pegasparaginase infusion



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CONTACT INFORMATION

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