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NO IMPACT OF PROPHYLACTIC CORTICOSTEROID USE IN PATIENTS RECEIVING AXICABTAGENE CILOLEUCEL FOR LARGE B-CELL LYMPHOMA

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INTRODUCTION

- Axicabtagene ciloleucel (axi-cel) is associated with a high rate of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).
- A safety cohort group of the ZUMA-1 trial demonstrated improved safety profile with prophylactic corticosteroids with axi-cel; however, this data has not yet been evaluated in real-world practice.

METHODS

- We conducted a single-center, retrospective analysis of patients (pts) treated with axi-cel for relapsed or refractory (R/R) large B-cell lymphoma (LBCL) from 2018 through 03/2024 in order to examine the impact of prophylactic dexamethasone (dex ppx) on treatment-related toxicities associated with axi-cel.
- Incidence, severity, and duration of CRS and ICANS. Wilcoxon rank-sum test and pooled t test were utilized (two-sided P value of <.05) to determine the statistical significance of differences between variables.

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RESULTS

- 68 pts treated with axi-cel were identified. 14 treated with dex ppx, 53 without ppx, and 1 pt on prednisone 10 mg daily at the time of axi-cel infusion.
- There was no difference in age, stage of disease, LDH, IPI score, presence of extranodal disease, or use of bridging therapy between the two groups (Table 1).
- All pts who received dex ppx developed CRS (grade 1 n=7, grade 2 n=7) at a median onset of 3 days (range 1-12), and 71% (10/14) developed CRS within the first 72 hours after CAR T-cell therapy compared with 86.8% (46/63) pts who did not receive corticosteroid ppx (grade 1 n=21, grade 2 n=24, grade 3 n=1) at a median onset of 3 days (1-11).
- With dex ppx, 5 pts (35.7%) developed ICANS (grade 1 n=2, grade 3 n=2, grade 4 n=1) compared with 28 pts (52.8%) without dex ppx (grade 1 n=9, grade 2 n=9, grade 3 n=10).
- Median duration of ICANS was longer in patients who received ppx as compared with those who did not, 13 days (7-63) vs 5 days (1-57), respectively (P=0.006).

	All Patients (n= 68)	Dex Prophy (n= 14)	No Dex Prophy (n=53)	P-value
Age, yrs (range)	63 (24-86)	61 (40-81)	63 (24-86)	.90
Stage of Disease, n (%) Stage 1 Stage 2 Stage 3 Stage 4	 3 (4.4) 7 (10.3) 10 (14.7) 48 (70.6)	 - 1 (7.1) 3 (21.4) 10 (71.4)	 3 (5.7) 6 (11.3) 7 (13.2) 37 (69.8)	.74
Elevated LDH, n (%)	30 (44.1)	3 (21.4)	26 (49.1)	.06
Median LDH, U/L (range)	259 (134-3932)	234 (137-1140)	263 (134-3932)	.17
ECOG PFS, n (%) ECOG 0 ECOG 1 ECOG 2 ECOG 3	 26 (38.2) 34 (50.0) 5 (7.3) 2 (2.9)	 6 (42.9) 8 (57.1) - -	 19 (35.8) 26 (49.1) 5 (9.4) 2 (3.8)	.96
Extranodal Disease, n (%)	52 (76.5)	10 (71.4)	41(77.4)	.64
CNS Disease, n (%)	1 (1.5)	0	1 (1.9)	-
IPI Score, n (%) IPI 1 IPI 2 IPI 3 IPI 4	 10 (14.7) 19 (27.9) 23 (33.8) 11 (16.2)	 2 (14.3) 1 (7.1) 8 (57.1) 1 (7.1)	 8 (15.1) 17 (32.1) 15 (28.3) 10 (18.9)	.09
Bridging Therapy, n (%)	41 (60.3)	10 (71.4)	30 (56.6)	.31

	All Patients (n= 68)	Dex Prophy (n= 14)	No Dex Prophy (n=53)	P-value
CRS				
Incidence, n (%)	60 (88.2)	14 (100)	46 (86.8)	0.49
Median time to onset, days (range)	3 (1-12)	3 (1-12)	3 (1-11)	0.86
Median duration, days (range)	4 (0-10)	5 (1-9)	4 (0-10)	0.44
Max grade, n (%) Grade 1 Grade 2 Grade 3 Grade 4	 28 (46.7) 31 (51.7) 1 (1.6) 0	 7 (50) 7 (50) 0 0	 21 (45.7) 24 (52.1) 1 (2.2) 0	0.83
ICANS				
Incidence, n (%)	33 (48.5)	5 (35.7)	28 (52.8)	0.25
Median time to onset, days (range)	6 (1-19)	4(1-8)	7 (2-19)	0.24
Median duration, days (range)	6 (1-63)	13 (7-63)	5 (1-57)	0.006
Max grade, n (%) Grade 1 Grade 2 Grade 3 Grade 4	 11 (33.3) 9 (27.3) 12 (36.4) 1 (3.0)	 2 (40) - 2 (40) 1 (20)	 9 (32.1) 9 (32.1) 10 (35.7) -	0.21

CONCLUSIONS

Dex ppx did not impact incidence, severity, or duration of either CRS or ICANS in patients treated with axi-cel for R/R LBCL. The significance of these findings is limited by the retrospective, single-center data and limited sample size but warrants validation in a larger cohort.