Real-World Patient-Reported Outcomes Among Recipients of Axicabtagene Ciloleucel for Relapsed/Refractory Large B Cell Lymphoma

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Introduction

- Limited data exist regarding patient-reported outcomes (PROs) of chimeric antigen receptor (CAR) T-cell therapy, with no published longitudinal studies to our knowledge reporting on patients treated as standard of care.
- The goal of the current study was to report on real-world changes in PROs (i.e., patient-reported symptoms and quality of life [QoL]) in the first year after treatment with axicabtagene ciloleucel (axi-cel).

Methods

Participants

- Eligible patients: a) were 18 years of age or older; b) were scheduled to receive axi-cel as standard of care at Moffitt Cancer Center for diffuse large b-cell lymphoma, primary mediastinal b-cell lymphoma, or transformed follicular lymphoma; c) were able to speak and read English; d) had no documented or observable psychiatric or neurological diagnoses that interfere with study participation; and e) were able to provide informed consent.
- Patients were identified through clinic schedules and tumor board in consultation with the treating oncologist.
- Participants were recruited between March 2020 and June 2022.

Procedure and Measure

- This prospective, single-center study was approved by the Advarra IRB (Pro00040160).
- Patients were consented and the baseline questionnaire was completed prior to conditioning therapy before axi-cel.
- Follow-up questionnaires were completed at 14, 30, 60, 90, 180, and 360 days post-infusion of axi-cel.
- QoL and symptomatology in the past week was assessed with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30).[1] Higher scores on the quality of life subscales indicate better quality of life; higher scores on the symptom items indicate greater symptomatology.

Analyses

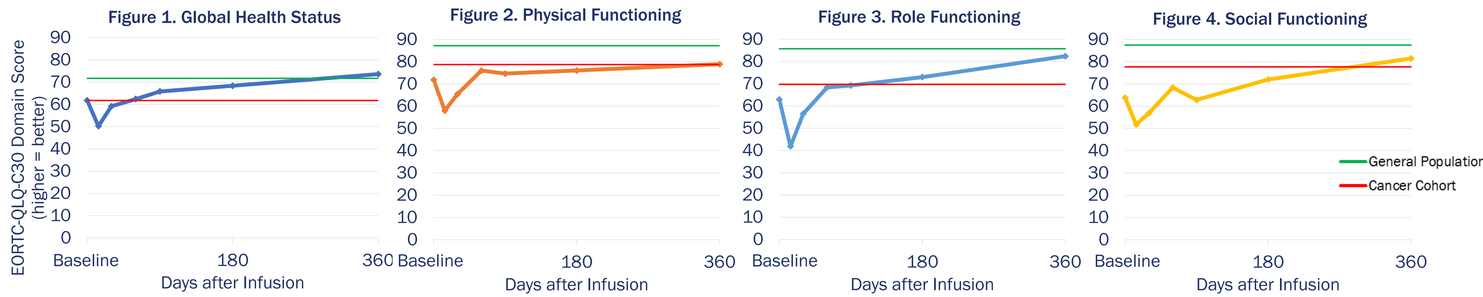
- Random effects mixed models evaluated change in EORTC global quality of life and symptom subscales using all available data.
- Clinically meaningful change was defined as a difference of 10 points, consistent with previous studies.[2]

Table 1. Participant characteristics (n=53)

Demographic Characteristics	n (%)	Clinical Characteristics	n (%)
Age: mean (SD)	63.23 (12.76)	Lymphoma type	
Female	20 (38%)	Diffuse large B-cell	36 (72%)
Non-Hispanic	49 (96%)	Transformed follicular	7 (14%)
White	49 (94%)	Follicular	7 (14%)
Married	32 (62%)	Eligible at apheresis for ZUMA-1*	32 (64%)
College graduate	31 (58%)		

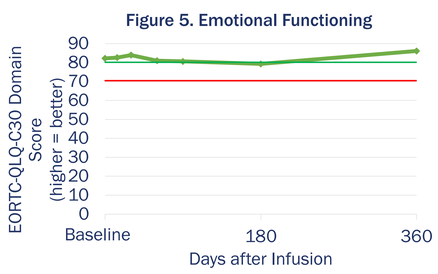
*ZUMA-1 was a pivotal phase 1/2 multicenter trial of axi-cel that was completed before the current study opened. Eligibility data for ZUMA-1 is provided as a point of comparison to previously-published data.[3]

Results



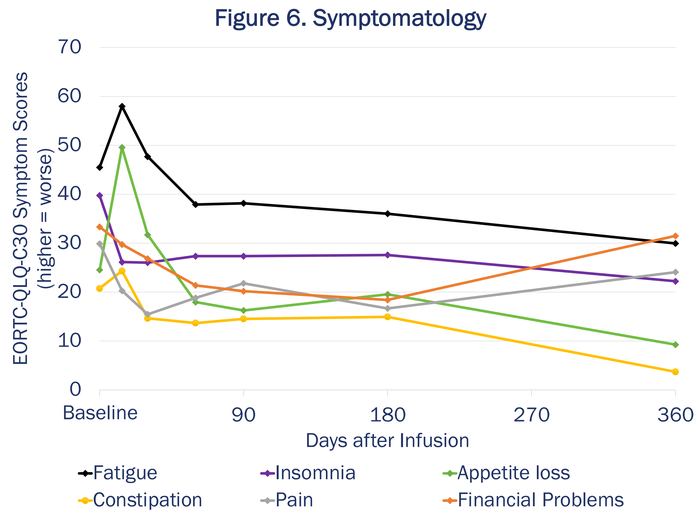
Improved Quality of Life

- Results demonstrated that among patients with EORTC data (baseline n=53, day 14 n = 37, day 30 n = 41, day 60 n = 39, day 90 n = 39, day 180 n = 29, day 360 n = 18), global health scores, physical functioning, role functioning, social functioning, and emotional functioning improved significantly over time.
- Global health scores matched cancer patient norms for age 50-70 at baseline and improved over time, exceeding general population norms for age 50-70 by 360 days after axi-cel.[4]
- Scores for physical functioning, role functioning, and social functioning improved from below cancer patient norms at baseline to at or above cancer patient norms by 360 days after axi-cel.
- Emotional functioning worsened gradually from baseline to 180 days but improved thereafter and exceeded general population norms at 360 days after axi-cel.



Reduced Symptom Severity

- Results of the mixed models demonstrated that fatigue, insomnia, appetite loss, and constipation improved significantly from baseline to 360 days after axi-cel.
- In contrast, improvements in pain and financial problems were followed by worsening thereafter.



Conclusions

- Real-world data suggest that axi-cel is associated with transient worsening of quality of life and symptoms at day 14, with significant improvements thereafter in overall quality of life and several functional and symptom domains.
- These data are generally consistent with PROs reported from clinical trials of CAR T-cell therapy, even though 36% of patients were not eligible for ZUMA-1 at apheresis. Findings extend previous research by reporting on patients' perspectives on CAR T-cell therapy received as standard of care in the real-world setting.
- Later timepoints may be influenced by subsequent treatments or other health conditions for some patients.

[1] Fayers et al. *Eur J Cancer.* 2002; [2] Osoba et al. *J Clin Onc.* 1998;
[3] Locke et al. *Mol Ther.* 2017; [4] Quinten et al. *Eur J Cancer*. 2015