

patients experienced two recurrences of 30-d MACE (1 ARI and 2 NCMP).

As displayed in the Table, age >60 years, baseline echocardiographic diastolic dysfunction, earlier start of CRS, CRS  $\geq$  grade 3, long duration of CRS, and use of tocilizumab were significantly associated with an increased risk of 30-d MACE.

No association between timing and/or magnitude of C-reactive protein or ferritin peak and occurrence of MACE was observed.

After a median follow-up time of 16.2 months (range 14.3-19.1) for censored observations, the occurrence of 30-d MACE was not significantly associated with progression-free survival (PFS) (p-value = 0.55, log-rank test), or with overall survival (OS) (p-value = 0.52, log-rank test).

**Conclusions:** Our results suggest that the occurrence of 30-d MACE is more frequent among patients who are elderly, with baseline diastolic dysfunction, early, severe and prolonged CRS, but had no statistically significant impact on PFS and OS. However, with limited follow-up, larger prospective studies are needed, and multidisciplinary management of these patients is recommended.

**Keywords:** Aggressive B-cell non-Hodgkin lymphoma, Cellular therapies

Conflicts of interests pertinent to the abstract

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## 266 | PATIENT-REPORTED QUALITY OF LIFE (QOL) FOLLOWING TISAGENLECLEUCEL (TISA-CEL) INFUSION IN ADULT PATIENTS (PTS) WITH RELAPSED/REFRACTORY FOLLICULAR LYMPHOMA (R/R FL)

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**Introduction:** Patient-reported QoL is an important endpoint in the single-arm phase II ELARA trial of tisa-cel, which has demonstrated efficacy and favorable safety profiles in adult pts with r/r FL (Fowler NH et al, ASH 2020). Here, we present patient-reported QoL data before and after tisa-cel infusion in ELARA.

**Methods:** Eligible pts ( $\geq 18$  y) had r/r FL (grades 1-3A) after  $\geq 2$  lines of therapy or had failed autologous stem cell transplant (autoSCT). Pts completed the Functional Assessment of Cancer Therapy-Lymphoma (FACT-Lym) and Short Form-36 Health Survey v2 (SF-36) at baseline, and at Months (Mo) 3 and 6 post tisa-cel infusion. For both instruments, a change score  $>0$  indicated improved QoL.

**Results:** As of September 28, 2020, 98 pts were enrolled and 97 received tisa-cel (median follow-up, 10.6 mo); 75% of pts had previously received  $\geq 3$  prior lines of therapy and 36% had relapsed after autoSCT. QoL instruments were completed by 79 pts (81%) at baseline, including 69 pts who had a complete or partial response. FACT-Lym and SF-36 assessments were completed by 71 (74%) and 68 (71%) pts at Mo 3 and by 61 (65%) and 60 (64%) pts at Mo 6, respectively. The FACT-Lym subscales showed improvement in the emotional, functional, and physical domains. Furthermore, no deterioration in the social/family domain by Mo 6 was reported, although minimal clinically important differences of 2 were not reached. Similarly, numeric improvement was observed in mean change scores from baseline through Mo 3 for the SF-36 mental health component scores and through Mo 6 for the physical health component scores, including general health, vitality, physical functioning, role-emotional, and role-physical. Overall, 40%-49% of pts demonstrated clinically meaningful improvements in QoL based on FACT-Lym and SF-36 at Mo 3. Furthermore, 68%-83% of pts' QoL did not deteriorate (Table). Similar trends were observed at Mo 6. Additionally, mean

Visit	Parameter	MID	Deteriorated, n (%)	Improved, n (%)
<b>Month 3</b> (n=63) <sup>a</sup>	FACT-G TS	3-7	19 (30)	31 (49)
	Lym Subscale <sup>b</sup>	2.9-5.4	11 (17)	29 (45)
	FACT-Lym TOI	5.5-11	13 (21)	25 (40)
	FACT-Lym TS	6.5-11.2	15 (24)	26 (41)
	SF-36 PCS	3	20 (32)	25 (40)
	SF-36 MCS	3	17 (27)	27 (43)
<b>Month 6</b> (n=56) <sup>a</sup>	FACT-G TS	3-7	21 (38)	24 (43)
	Lym Subscale	2.9-5.4	12 (21)	25 (45)
	FACT-Lym TOI	5.5-11	13 (23)	21 (38)
	FACT-Lym TS	6.5-11.2	16 (29)	25 (45)
	SF-36 PCS	3	14 (25)	25 (45)
	SF-36 MCS	3	17 (30)	19 (34)

<sup>a</sup>Patients with non-missing change from baseline at that visit. <sup>b</sup>Among 64 patients. FACT-G, FACT-General; FACT-Lym, Functional Assessment of Cancer Therapy-Lymphoma; TOI, Trial Outcome Index; TS, Total Score; MID, minimal important difference; MCS, Mental Component Score; PCS, Physical Component Score; SF-36, Short Form-36.

change scores for FACT-Lym improved from baseline to Mo 3 and to Mo 6.

**Conclusions:** These results demonstrate that clinically meaningful improvements in QoL were observed in pts post tisa-cel infusion.

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**Keywords:** Indolent non-Hodgkin lymphoma, Cellular therapies

**Conflicts of interests** pertinent to the abstract

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