EHA EUROPEAN HEMATOLOGY ASSOCIATION

EHA2024 JUNE 13 - 16 | MADRID

T²EVOLVE QUALITOP

Patient-reported outcomes of CAR T-cell therapy: an international European study evaluating patients' experiences, quality of life and unmet care needs

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INTRODUCTION

- Chimeric Antigen Receptor T-cell therapy (**CAR-T**) has emerged as a **new pillar in cancer treatment**, with impressive response rates in patients with **relapsed or refractory B-cell malignancies**.
- Direct insights from patients – **patient-reported outcomes (PROs)** – contribute to a more comprehensive evaluation of novel therapies and are **fundamental to enable patient-centered care**.
- Although the CAR-T field is rapidly advancing, **PROs are still underreported**.
- Therefore, CAR-T and quality of life (QoL) experts from the European consortia T2EVOLVE and QUALITOP in close collaboration with patient organisations, patients, and caregivers, have set up a **large international cross-sectional survey study** to collect PROs from patients who received CAR-T for hematologic malignancies in Europe.

AIM

This study was developed to better understand patients' experiences with CAR-T, evaluate the impact on QoL and identify unmet needs

METHOD

- The survey comprised **both validated questionnaires** and **ad hoc items** (mainly multiple choice).
- It covered the following topics:
  1. Demographics
  2. Disease and treatment characteristics
  3. CAR-T treatment experience
  4. Supportive care
  5. Stress and anxiety (PCL-5)
  6. QoL (EQ-5D-5L, EORTC QLQ-C30)
  7. Working life (modified iPCQ)
  8. Information and educational material
- **All European adult patients who received CAR-T for a hematologic malignancy could participate.**
- The survey was available online from **January–October 2023** in **7 languages**:

English French Dutch Spanish Italian German Portuguese

- It was disseminated by CAR-T treating physicians, patient organizations, the T2EVOLVE Working Group of Patients & Caregivers and T2EVOLVE and QUALITOP consortium members
- Descriptive statistics and linear regression models were used for analyses.

RESULTS (1)

Table 1. Patient characteristics

CHARACTERISTICS	European CAR-T patients (N=389)
Age, median (min-max)	61 years (18-85)
Female, %	37
Diagnosis, Lymphoma, %	86
Multiple myeloma, %	8
Leukemia, %	6
Unknown, %	1
Time since CAR-T infusion, ≤3 months, %	16
4 - 12 months, %	27
13-24 months, %	25
>24 months, %	31
Treatment setting, Clinical trial, %	34
Standard of care, %	60
Unknown, %	7
Received bridging therapy[a], %	55
Hospital admission duration, median (min-max)	16 days (0-210)
Admitted to ICU, %	24
Experienced cytokine release syndrome, %	62
Experienced neurologic side effects, %	42
Experienced infections, %	26
Experienced cytopenia(s), %	75
Disease progression after CAR-T, %	20

[a] Not applicable for the patients who received allogeneic CAR T-cells (n=4)
ICU Intensive Care Unit

Figure 1. Patients per country (N=389)

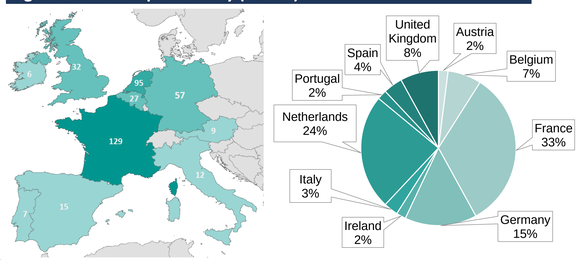
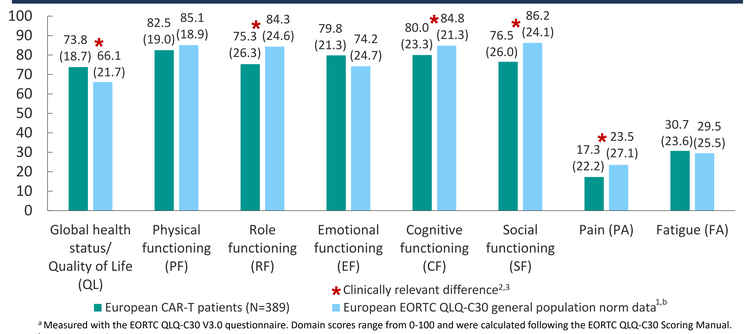


Figure 2. Quality of Life - EORTC QLQ-C30 mean domain scores (standard deviation; sd) for the European CAR-T patients and the European EORTC QLQ-C30 general population norm data[1,a]



[a] Measured with the EORTC QLQ-C30 V3.0 questionnaire. Domain scores range from 0-100 and were calculated following the EORTC QLQ-C30 Scoring Manual.
[b] Not matched for age, sex or country.

Figure 3. Proportion of patients experiencing anxiety (yellow) and impact of this anxiety on their everyday life (purple)

Anxiety regarding disease recurrence/ progression (A), long term adverse events (B), getting an infection (C) and COVID-19 in particular (D)

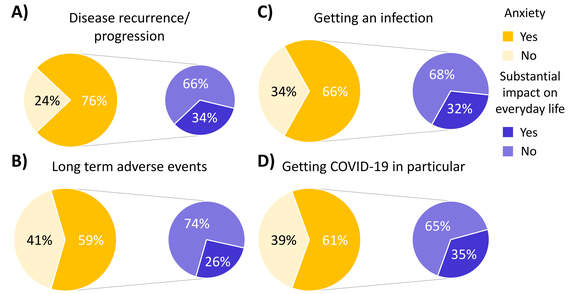
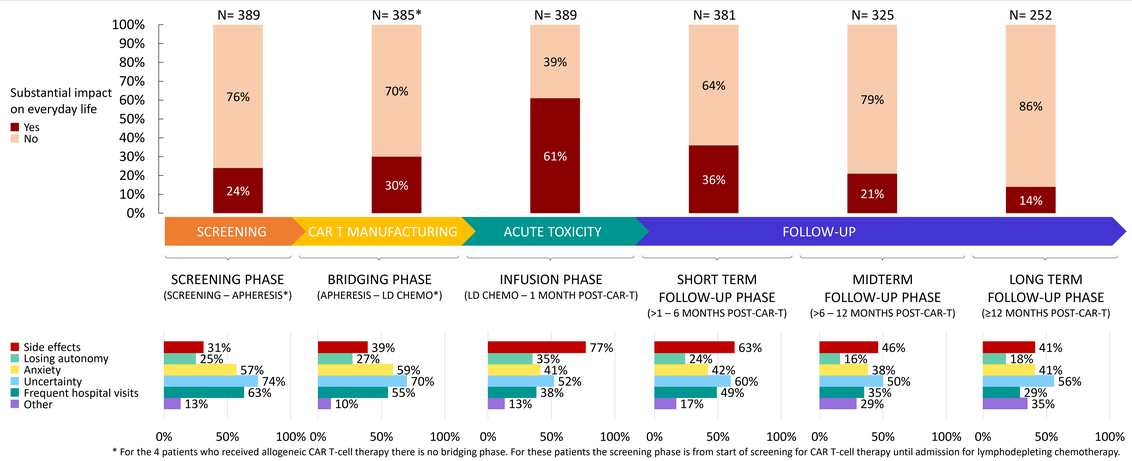


Figure 4. Impact of the different CAR-T treatment phases on everyday life and reasons for a substantial impact on everyday life



* For the 4 patients who received allogeneic CAR T-cell therapy there is no bridging phase. For these patients the screening phase is from start of screening for CAR T-cell therapy until admission for lymphodepleting chemotherapy.

RESULTS (2)

- **Patients >2 years post-CAR-T had clinically relevant improved QoL (QL domain) compared to patients ≤3 months post-CAR-T** (mean score: 79.0 vs 70.3). This difference was **statistically significant** corrected for sex, age (≤70 vs >70), ICU admission, neurologic side effects and progression after CAR-T.
- The **mean EQ-5D-5L VAS-score** was **73.1** (sd: 18.5).
- Of all patients**, 4%** met the criteria for a **provisional PTSD** diagnosis.
- If patients indicated they would have appreciated to have received more support, **mental support** was mentioned most often.

CONCLUSIONS

- This is the **largest European study evaluating PROs on CAR-T in hematologic malignancies**.
- Reported **general QoL, emotional and physical functioning, level of pain and fatigue were similar or better than the general population**, whereas **role, social, and cognitive functioning were lower**.
- Although, in general QoL after CAR-T is relatively good, CAR-T can have a **substantial impact on everyday life** and a **considerable proportion of patients experience stress or anxiety**, emphasizing the importance of **adequate support** during CAR-T treatment.

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ACKNOWLEDGEMENT

The authors would like to thank all patients and their caregivers, who play a very important role in supporting patients.

This research was funded by the Innovative Medicines Initiative 2 Joint Undertaking (grant agreement No. 116026), T2EVOLVE, this Joint Undertaking receives support from the European Union's Horizon 2020 Research and Innovation program and European Federation of Pharmaceutical Industries and Associations (EFPIA), and by European Union's Horizon 2020 research and innovation program under grant agreement No. 875171, QUALITOP.

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