Continuous wearable monitoring post CAR-T can identify CRS earlier than standard of care.

Wearable digital health technologies (DHT) detected CRS at least 13 hours prior to intermittent monitoring (SoC) in patients undergoing CAR-T cell therapy.

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EARLIER CRS IDENTIFICATION WITH CONTINUOUS WEARABLE MONITORING IN OUTPATIENT CAR-T CELL THERAPY

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BACKGROUND

- CAR T cell therapy has transformed outcomes of hematologic malignancies and is poised to expand into solid malignancies.
- However, broader use of CAR T remains constrained by the need for timely cytokine release syndrome (CRS) detection. Current episodic monitoring may miss early physiologic changes.
- Wearable digital health technologies (DHTs), offering continuous monitoring and real time alerts, could enable earlier CRS detection, further support outpatient delivery, and expand access to CAR T and potentially other immunotherapies associated with CRS.

METHODS

- This single-center observational study (NCT05018208) enrolled patients receiving FDA-approved CAR-T products in the outpatient setting at Mayo Clinic, Rochester MN.
- Management of post-CAR-T complications (e.g. CRS) followed the institution's standard of care.
- Patients were monitored from day -5 to day +30 post infusion with intermittent remote patient monitoring (SoC) and an arm-worn wearable device for continuous monitoring (DHT).
- Patients were included in this analysis if DHT data were available for ≥ 5h of data/day or ≥ 2h of data/night on ≥2 days or nights for baseline and ≥1 day or night within 72h prior to CRS, or at least 2h within 4h of CRS onset, or if DHT was available for ≥7 days/nights post infusion with no CRS event.
- CRS detection time by DHT was defined as the onset of pyrexia or threshold-based deviation from an individual's baseline pulse distributions.

RESULTS

- 32 patients were included in this report (median age 64 years, gender 12 F/20 M, diagnoses 18 MM/14 NHL).
  - 25 patients experienced a CRS event, with maximum CRS grades ranging from 1-3 (16 G1, 8 G2, 1 G3).
    - 24/25 patients with CRS required tocilizumab/steroid. Median CRS onset time was 3.4 days (range 0.4-18.4).
- 12/32 patients had sufficient DHT data (7 CRS, 5 no CRS) for analysis. Two cases are highlighted in the figure below.
  - 5 patients with CRS had a DHT detection time in advance of the SoC by a median of 13h (range 2.8 - 69.2).
    - The DHT prediction of CRS by baseline HR change was earlier than the first episodic fever by a median of 14.5h (range 13-77.5).
  - The remaining 2/7 patients who did not have CRS detected by the DHT had missing DHT data for more than 45h before a treated CRS event.
- DHT detected CRS in 2/5 patients without CRS according to SoC.
  - One patient had fever caught with intermittent monitoring. The other was treated for neutropenia fever with suspicion of CRS and/or infection.

CONCLUSION

- These results offer evidence that continuous DHT can identify CRS events earlier than intermittent monitoring (SoC).
- Despite limitations related to compliance with wearable device use and data missingness, and variability in clinical management of CRS, we highlight the usability of DHT and its potential for future studies with optimized strategies to address these limitations.

FIGURE

