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Background

- CAR T-cell therapy has been a major innovative breakthrough for hematologic malignancies with 2 currently FDA-approved CAR T-cell products (tisagenlecleucel[1] and axicabtagene ciloleucel[2]) and several others in different stages of clinical investigation.
- CAR T-cell therapies are associated with unique safety profiles and potentially serious toxicities, including cytokine-release syndrome (CRS) and immune effector cell-associated neurotoxicity (ICANS).
- These adverse events (AEs) require vigilant monitoring and prompt recognition and management to ensure patient safety and optimal therapeutic benefit.
- CCO developed an online Interactive Decision Support Tool to give healthcare providers (HCPs) case-specific, evidence-based consensus recommendations from a panel of interdisciplinary experts on the management of AEs due to CAR T-cell therapy.

Methods

- Here, we report an updated comparison of planned CAR T-cell toxicity management among HCPs using the tool vs the expert consensus recommendations in the tool in the first 231 cases entered from 5/9/2019 through 9/18/2019 (Cohort 1) and the next 200 cases entered from 9/19/2019 through 7/31/2020 (Cohort 2).

Results

- **Cohort 1:** Significant difference in concordance by grade (P = .0417).
- **Cohort 2:** No significant difference in concordance by type of AE, grade of AE, or by region (US vs non-US HCPs).

Demographics and Cases Entered

<table>
<thead>
<tr>
<th>Grade</th>
<th>US HCPs (n = 38)</th>
<th>Non-US HCPs (n = 52)</th>
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Impact of the Tool on Clinical Practice

- Of the 53 HCPs who answered the optional impact survey questions, 50% in Cohort 1 and 76% in Cohort 2 indicated that the tool recommendations confirmed their management plan.
- The proportion of the type of HCPs using the tool was comparable in both Cohorts.
- 76% in Cohort 2 indicated that the tool recommendations confirmed their management plan.
- Only 60% of HCPs' planned management of specific AEs was concordant with expert recommendations provided in the tool in Cohort 1 vs 55% in Cohort 2.

Concordance of HCP Toxicity Management With Expert Recommendations

- In Cohort 1, 60% of cases managed concordant with expert recommendations (n = 54).
- In Cohort 2, 55% of cases managed concordant with expert recommendations (n = 54).

**Graphs and Tables**

- CRS Neurotoxicity Total
- Impact of the Tool on Clinical Practice
- CRS Case Management, by Grade (n = 126)
- CRS Cases
- CRS Grade
- CRS Neurotoxicity

Conclusions

- These data suggest that many HCPs continue to suboptimally manage AEs associated with CAR T-cell therapy administration.
  - Only 60% of HCPs' planned management of specific AEs was concordant with expert recommendations provided in the tool in cohort 1 vs 55% in Cohort 2.
  - In cohort 1, there was a significant difference in concordance with expert recommendations by grade, however, no significant difference was found in cohort 2 by grade, type of AE (CRS vs ICANS), or by region (US vs non-US HCPs).
  - Tocilizumab was used more frequently by HCPs than expert recommendations for management of ICANS.
  - Corticosteroids were used earlier in CRS (lower grades).
  - Use of an online tool providing interactive, case-specific, evidence-based consensus recommendations can improve patient care and safety.
  - A greater proportion of HCPs in Cohort 2 indicated that the expert recommendations confirmed/matched their intended management plan (76% vs 50% in Cohort 1) indicating potentially improved confidence in CAR T-cell therapy toxicity management over time.

References


The tool is online at: clinicaloptions.com/cartool

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