Patient-Reported Outcomes in T-Cell Lymphoma Trials

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Introduction

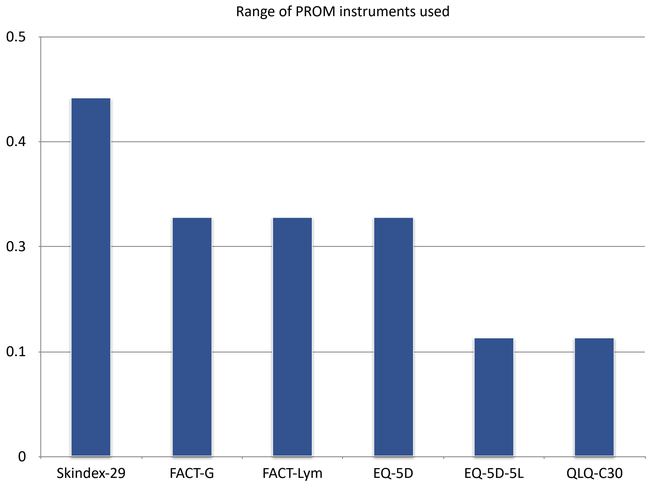
T cell lymphomas represent 10-15% of all non-Hodgkin lymphomas, with an estimated 10,000 to 15,000 new cases annually in the United States.PROM are increasingly used in clinical trials to complement traditional end points such as overall survival and progression free survival

Objective

We aimed to examine trends in the inclusion of PROMs as outcome measures in clinical trials involving T-cell lymphomas.

Methods

- We conducted a systematic review of clinicaltrials.gov to identify completed phase 2,3 and 4 clinical trials involving patients with T-cell lymphoma
- We screened each entry to determine whether PROMs were listed as either primary or secondary endpoints
- Extracted variables included trial phase, date of completion, PROM usage, type of PROM tool used and basic demographic characteristics of enrolled participants.



Results

- A total of n=216 trials met the inclusion criteria.
- Only 3% (n=7) of trials included PROMs, all of them listed them as secondary outcomes
- The trials reporting PROMs were conducted between June 2012 and January 2024
- Across these studies, the mean participant age was 59.4 years and 54.9% of the participants were male.
- Ethnic distribution was predominantly White (64.3%), followed by Black (6.2%) and Asian (5.2%).
- A range of PROM instruments were employed, with Skindex-29 being the most commonly used (42.8%), followed by FACT-G, FACT-Lym, and EQ-5D (each used in 28.5% of studies), as well as EQ-5D-5L and QLQ-C30 (each in 14.2%)

Discussion

This study is the first to examine the use of patient-reported outcome measures (PROMs) in T cell lymphoma trials, revealing that only 3% of completed phase 2-4 trials included them, exclusively as secondary outcomes. The wide variation in PROM tools limits comparability and weakens patient-centered assessment. These findings underscore the urgent need for standardized, validated PROM integration to ensure clinical trials capture outcomes that reflect patients' lived experience.

References

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