PCR136

Defining Treatment Tolerability from the Patient's Perspective: A Mixed-Methods Analysis of the Cancer Experience Registry

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OBJECTIVES

- Treatment tolerability is a critical consideration in oncology, where therapies are often associated with substantial toxicity and side-effect (SE) burden. While tolerability has traditionally focused on the extent to which observable side effects can be endured, multi-stakeholder organizations and regulatory agencies such as the FDA and EMA increasingly emphasize the importance of incorporating patient experience data into benefit–risk assessments.[1, 2, 3, 4]
- Adult cancer survivors who participated in the Cancer Experience Registry (CER) of the Cancer Support Community (CSC) provided their perspectives on tolerability.[5] They defined treatment tolerability (Q1) by mentioning treatment SEs (40.4%), quality of life (QoL) impacts (32.7%), and the ability to manage treatment and side effects (19.5%). Additionally, they reported that the most important factors to consider when assessing tolerability (Q4) were SEs (76.6%), burden of treatment (59.3%), and positive treatment outcomes (54.7%), including treatment effectiveness (29.9%) or becoming cancer-free (11.8%).[5]
- This study presents the results of a secondary survey analysis which aimed to assess the influence of age and time since diagnosis on cancer survivors' definition and prioritization of tolerability-related concepts.

METHODS

- Data were drawn from the CER, a longitudinal online survey of >4,000 adult cancer survivors across the U.S. and Canada. CER is the CSC's online survey platform. At the 24-month follow-up, participants were asked to complete treatment tolerability items (including Q1 and Q4 below).
- Descriptive statistics summarized quantitative responses, while free-text data were analyzed using a deductive–inductive qualitative approach. Coding in MAXQDA (VERBI Software) was used to tag tolerability-related concepts, organize participant quotes, and identify conceptual domains of interest. The study was IRB-approved and participants provided informed consent.

RESULTS

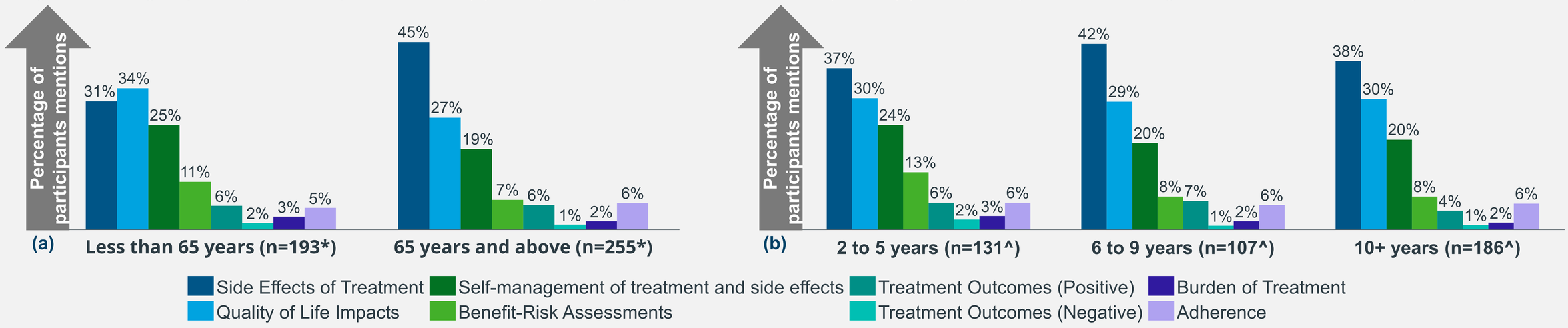
- Participants who completed the survey in December 2023-February 2024 (N=492) resided in US and Canada, and were predominantly White women aged ≥65 years (median time since diagnosis=8.0 years; range 2–51 years), with diverse cancer diagnoses. Most had not received treatment in the past six months (61.3%).

Q1: "If we asked you whether your treatment is tolerable, what would you think we were asking?"

Results showed that participants aged ≥65 years were more likely to associate tolerability with **SEs** than younger participants, for which **QOL impacts** were more frequently mentioned (Figure 1a).

When participants were categorized according to time since diagnosis (2-5, 6-9 and 10+ years), all groups defined tolerability (Q1) by frequently mentioning **SEs**, **QoL impacts**, and the **ability to manage treatment and side effects of treatment** (Figure 1b).

Figure 1: Subgroup analysis of response to Q1: (a) analysis by age at the time of survey, and (b) analysis by time since diagnosis at the time of survey



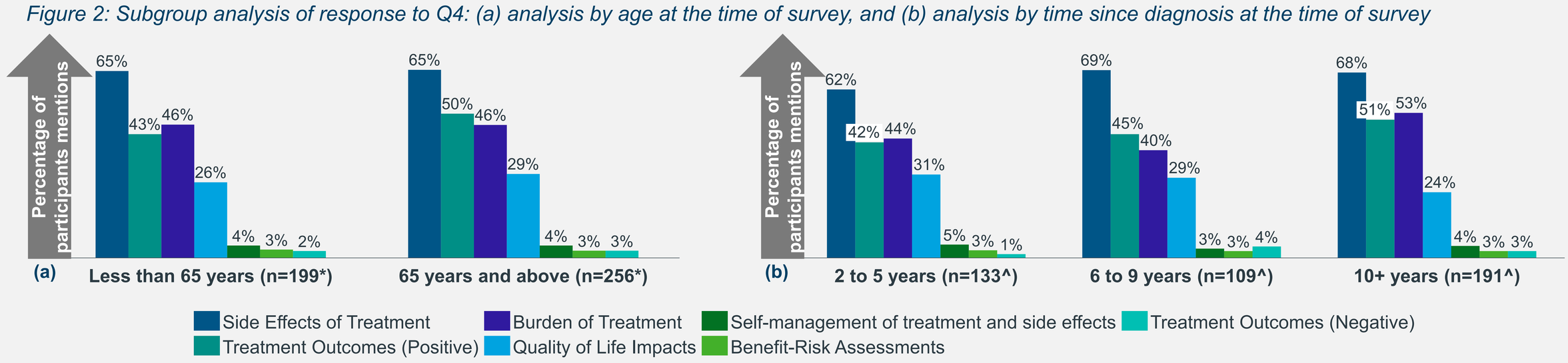
NOTE: The total percentage of mentions within each group may exceed 100%, as individual participants often shared multiple concepts;
**Excluding N=44 (n=17 in <65 years and n=27 in >65 years) did not respond to Q1*

NOTE: Time since diagnosis was not available/missing for n=26 participants;
^Excluding N=44 (n=13 in 2 to 5 years, n=12 in 6 to 9 years, n=17 in 10+ years, and n=2 from missing time of diagnosis) did not respond to Q1

Q4: "Please rank the top 3 factors that you take into consideration when evaluating whether a treatment is tolerable or not"

SEs, **positive treatment outcomes**, **burden of treatment** and **QoL impacts** were the most frequently selected factors across age groups and different periods of time since diagnosis (Figures 2a and 2b).

Figure 2: Subgroup analysis of response to Q4: (a) analysis by age at the time of survey, and (b) analysis by time since diagnosis at the time of survey



NOTE: The total percentage of mentions within each group may exceed 100%, as individual participants often identified multiple concepts;
**Excluding N=37 (n=11 in <65 years and n=26 in >65 years) did not respond to Q4*

NOTE: Time since diagnosis was not available/missing for n=26 participants;
^Excluding N=37 (n=11 in 2 to 5 years, n=10 in 6 to 9 years, n=12 in 10+ years, and n=4 from missing time of diagnosis) did not respond to Q4

CONCLUSIONS

This survey demonstrated that treatment tolerability is not exclusively defined by **SEs** but reflects a multidimensional construct. Across age and time-since-diagnosis subgroups of cancer survivors, tolerability was mainly defined by **SEs**, **QoL impacts** and **self-management of treatment and SEs**, with older participants (≥65 years) placing more emphasis on **SEs**. Important factors for cancer survivors when evaluating treatment tolerability, were mainly driven by balancing **SEs** as the primary driver, with **perceived benefits** and **treatment burden** (e.g., treatment affordability and convenience), while **QoL** played a smaller but still relevant role. Together, these findings underscore the importance of incorporating patient-reported perspectives, including age-related differences, into tolerability assessment in clinical development, real-world evidence generation, and shared treatment decision-making.

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