Current Methods for Reporting Toxicities in Cancer Clinical Trials are Falling Short

Researchers recommend a greater focus on the cumulative effect of multiple low-level toxicities.

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New research from Europe, published in the December 2018 issue of *JNCCN—Journal of the National Comprehensive Cancer Network*, finds that quality-of-life for people with cancer is reduced by an accumulation of low-level toxicities just as much as it is from high-level adverse events. Additionally, patient-reported outcomes were more likely to reflect the impact on a patient’s physical well-being than those reported by their doctor.

“Incorporating patient-reported toxicity into routine cancer care will help make sure people with cancer get high-quality care with better symptom detection and management,” explained Claudia Schuurhuizen, MD, Amsterdam UMC Cancer Center Amsterdam. “These patient-reported outcomes appear to have a better correlation to patient quality-of-life. Our results also suggest that clinicians shouldn’t lose sight of lower grade adverse events. We want physicians to be more aware of how addressing lower grade toxicities can be just as important as higher ones for optimizing physical health status.”

Clinicians grade toxicity using the National Cancer Institute’s Common Terminology Criteria for Adverse Events (NCI-CTCAE) on a five-point scale, with higher numbers being worse and grade three and four generally indicating a need for clinical action. For example, in the case of vomiting, grade 1 correlates to one-to-two episodes of vomiting in 24 hours; grade 2 would be three-to-five episodes; grade 3 means more than six episodes, requiring a feeding tube or hospitalization; and grade 4 would be life-threatening consequences that need urgent intervention.

For this study, the researchers looked at 184 patients who were enrolled in a multicenter phase III randomized trial for patients with metastatic castrate-naïve prostate cancer between October 2004 and December 2008. Each patient completed quality-of-life assessments before treatment, as well as at three and six months in. Separate toxicity data were reported by both the patients and their clinicians.

According to the results, the strongest impact on quality-of-life came from cumulative toxicities, regardless of the grade. The researchers also found that patient-reported toxicity scores were
more associated with quality-of-life outcomes than clinician-reported scores.

“This study clearly demonstrates that patients self-report higher rates of toxicities when independently queried, compared with clinician-elicited toxicities during office visits,” said Terry S. Langbaum, Administrative Director, The Comprehensive Transplant Center, Johns Hopkins, and Patient Advocate, NCCN Guidelines Panel for Survivorship. “This may be due to a reluctance, on the part of patients, to ‘complain’ to their clinicians in a face-to-face encounter, especially when the symptoms are sensitive, such as impact on sexual function. Additionally, the significant differences in reporting may be due to less thorough inquiry on the part of the clinicians, who may be rushed for time during visits. If a full understanding of the impact of toxicities on quality-of-life is the goal, this study demonstrates that patients can self-report and grade their toxicities more completely in a setting independent of the office visit than clinicians can during a clinical encounter.”

Moving forward, the researchers would like to see reliable tools for assessing toxicity, particularly in patient-reported outcomes, used more frequently. They encourage the use of electronic data collection as one method for improving reporting rates and accuracy.

To read the entire study, visit JNCCN.org. Complimentary access to “Impact of Patient- and Clinician-Reported Cumulative Toxicity on Quality of Life in Patients With Metastatic Castration-Naïve Prostate Cancer” is available until March 10, 2019.

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