Changes in RECIST tumor measures correlate linearly with survival in patients treated with checkpoint inhibitors

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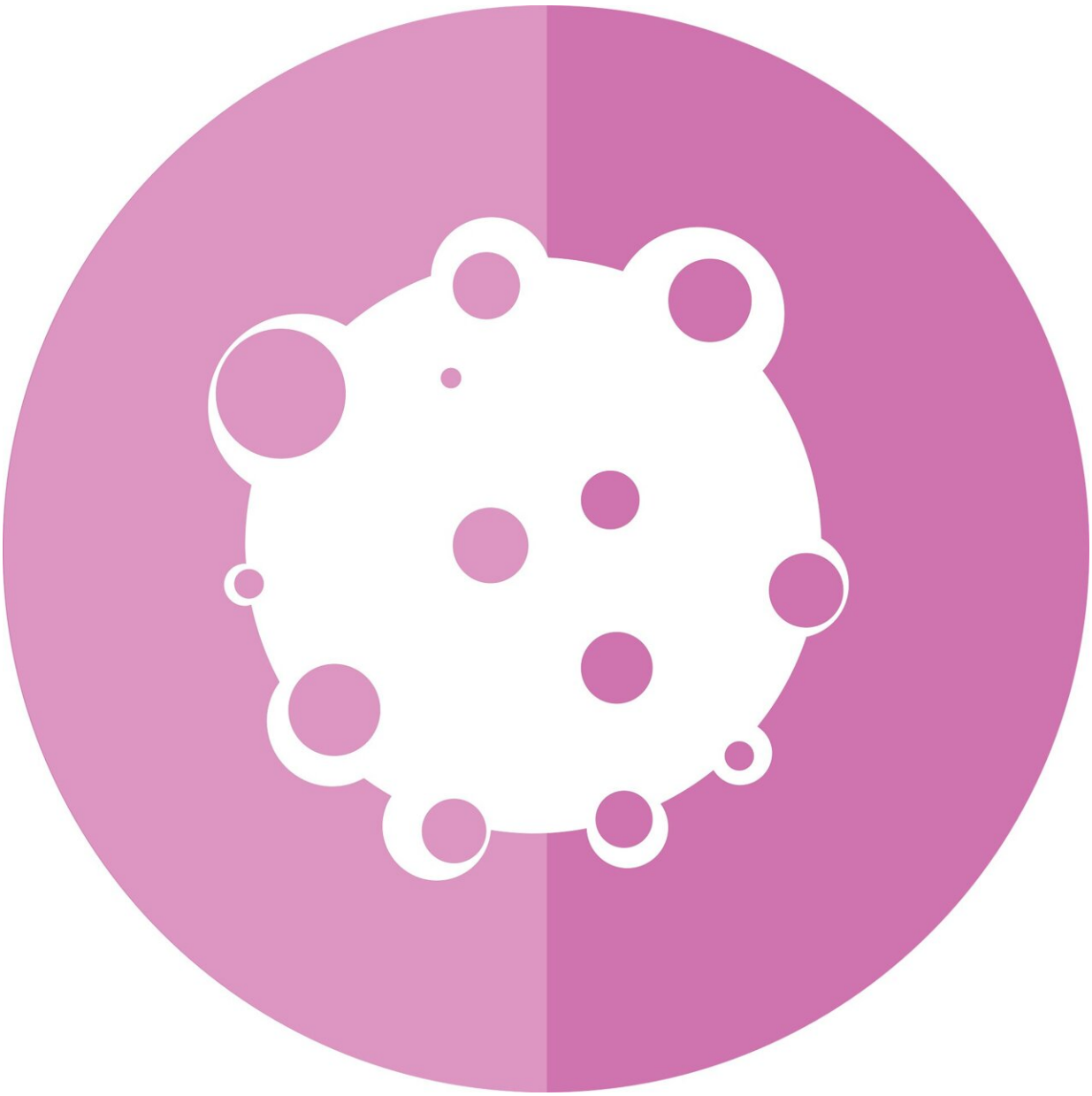

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The Response Evaluation Criteria In Solid Tumors (RECIST), used in many clinical trials to evaluate changes in tumor burden over time, classify objective tumor response into one of four categories (complete or partial response, or stable or progressive disease) based on the percent of change in the sum of the longest diameters of a set of target lesions.

An analysis of data from the SWOG S1609 trial conducted by the NCI-funded National Clinical Trials Network (NCTN) finds that in patients treated with immune checkpoint inhibitors, survival times correlate linearly with that change, rather than exhibiting threshold effects corresponding to those RECIST categories. This aligns with an earlier finding of a similar linear association with survival in patients treated with chemotherapy.

The results will be delivered in an oral presentation at the 2023 annual meeting of the American Society for Clinical Oncology (ASCO) in Chicago on June 4 by lead author Megan Othus, Ph.D., a biostatistician with the SWOG Statistics and Data Management Center and the Fred Hutchinson Cancer Center.

"I think that using just partial- and complete-response rate to define the 'success' of a trial can miss a signal," Othus said, "because patients who haven't achieved those levels of remission but also haven't progressed do have an outcome that is associated with longer survival."

Many early trials testing treatments in solid tumors rely on RECIST in measuring the effect the treatment has had on a patient's cancer. At

baseline, before a patient starts treatment, target lesions are identified—typically on CT or MRI scans—and their longest diameters are measured and totaled. This is the baseline value against which objective tumor response is evaluated.

In evaluating response from target lesions, the sum of these longest diameters must decrease by at least 30 percent for objective response to be categorized as a partial response. Tumor shrinkage by less than 30 percent is labeled stable disease.

To evaluate the association between quantitative change in RECIST tumor burden and patient overall survival and progression-free survival, Othus's team analyzed data from 720 patients with a variety of rare cancers who were treated with checkpoint inhibitor therapy on the S1609 DART (Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors) clinical trial. DART was a federally funded basket trial that evaluated the combination of ipilimumab (Yervoy) plus nivolumab (Opdivo) in treating 53 cohorts of patients with rare tumor subtypes.

For the analysis presented at ASCO, the researchers looked at the percent change in the sum of the longest diameters of target lesions between each patient's baseline assessment and their first scan after starting treatment. They used log-rank tests and Cox regression models to evaluate the association of those changes with patient overall survival and progression-free survival times.

Othus says the results are already having an impact on correlative work being done as part of the S1609 DART trial.

"We are using this finding to inform our translational medicine analyses," she said. "This increases the number of patients we are defining as having a 'good' outcome, which gives us more power to evaluate potential biomarkers associated with outcomes."

More information: Evaluation of change in RECIST tumor size and survival in patients with rare cancers treated with checkpoint inhibitor therapy (SWOG S1609), meetings.asco.org/abstracts-presentations/222691

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