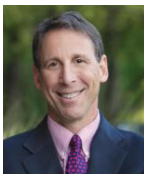
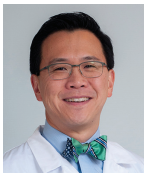
The Relationship Between Cardiovascular and Oncology Events in Clinical Trials: A Webinar Summary

Taking a look at cardiovascular and oncology events in clinical trials, there is an evident relationship between the two. Two leaders in the field explored this during the recent WCG webinar, "Examining the Relationship between both Cardiovascular and Oncology Events in Clinical Trials":



Jonathan Seltzer, MD, FACCC
Executive Director, Cardiac Safety Research Consortium, Former CEO and Founder of WCG ACI Clinical



Richard Lee, MD, PhD
Clinical Co-Director, The Claire and John Bertucci Center for Genitourinary Cancers Assistant Physician, Department of Medicine at Massachusetts General Hospital

ASSESSING CARDIOVASCULAR SAFETY EVENTS IN ONCOLOGY TRIALS

The fact that cancer therapies are cardiotoxic is nothing new. But as cancer survival rates increase and patients grow older, cardiotoxicity has become a more pressing concern. For people who have had cancer, their leading cause of death and morbidity is a secondary cancer. "However, after that, their leading cause of death is cardiac: Cancer patients get cardiovascular disease," Seltzer explained.

It's essential to protect against the actual CV risks of therapies and it's essential to clarify what is actual cardiotoxicity, he says. "The time has come for a little greater emphasis on more precision about cardiovascular events for patients in oncology trials," he said.

As a community, we must get better at making sure that we get diagnoses of cardiovascular events—not just signs and symptoms.

"In many cancer trials, treatment-related adverse events are recorded as signs, as symptoms rather than diagnoses."

In fact, one trial resulted in a therapy being taken off the market because of cardiac toxicity. However, it returned to the market after a retrospective analysis by an independent adjudication committee found many events had been mischaracterized as cardiovascular.

ASSESSING ONCOLOGY EVENTS DURING TRIALS EVALUATING CARDIOVASCULAR OUTCOMES

In the second part of the webinar, Lee moved the discussion to oncology events. "The flip side of this is also the increasing age of the population from improved treatment of cardiovascular disease and other diseases like diabetes increases the risk of being diagnosed with cancer."

This complicates efforts to determine whether these cancer outcomes are related to the drug in question. In adjudicating oncology events during clinical trials, there's much to consider, including:

1. **The drug:** Does it make sense for the drug's mechanism of action to cause malignant transformation? Does the timing make sense?
   - From drug exposure to malignant transformation
   - From malignant transformation to extent of disease
2. **The patient:** What confounders exist: genetics, age, smoking status, environmental exposures, etc.?
3. **Why or how was the diagnosis made?**

Adjudicating oncology adverse events is quite different from adjudicating cardiovascular events. For example, "unlike the rise of the cardio-oncology specialists that we have at cancer centers…not all centers that study cardiovascular-related diseases have site oncologists within reach," Lee said. "So in that sense, these events probably need to be adjudicated formally with experts."

Learn more

The webinar delved more deeply into these and other issues, and Seltzer and Lee also fielded questions from the live audience. To listen to it in its entirety, visit:

www.wcgclinical.com/events/cardiac-oncology-trials