

How Biomarkers Are Used in Melanoma

Measurable traits, such as genetic mutations, can guide treatment and help predict outcomes.

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The term “biomarker” is a frequent buzz word in cancer care circles, but many patients do not understand what a biomarker is and how they are used in the clinic. At the MRA 2022 Patient Forum, Dr. David Polsky of New York University took away much of the mystery surrounding biomarkers by deftly explaining what they are and how they enter the market, as well as by showing how physicians use biomarkers to guide therapy and predict outcomes in their patients.

What Are Biomarkers?

He reported that a biomarker is a measurable trait that can indicate a biological or disease-causing process, environmental exposure, or likely response to a treatment. For example, the BRAF mutation, found in about half of melanomas, indicates that the tumors have a genetic defect (mutation) that makes them likely to respond to the [therapies that target it](#). “This biomarker is so good that we don’t even offer [BRAF-targeted treatments] to patients unless they have the [BRAF] mutation,” he said.

Dr. David Polsky of New York University

Courtesy of Melanoma Research Alliance

Dr. Polsky also noted, however, that biomarkers can sometimes accurately reveal an important biological trait but still not be clinically useful. For example, the protein on tumor cells, PDL1, can serve as a biomarker for PD1 directed [checkpoint immunotherapies](#) (ie Nivolumab and Pembrolizumab). Patients with high amounts of it are more likely to respond well to PD1 immunotherapy and have better survival than those that lack it. However, a subset of patients with negligible levels of PDL1 may still respond well to immunotherapy — so the biomarker is not clinically useful for melanoma.

“There’s a high bar that has to be overcome to incorporate a biomarker into clinical practice,” Dr. Polsky stressed.

For a predictive biomarker, one that intends to “predict” if a patient will respond to a given therapy, researchers must show that the biomarker substantially impacts the outcome of patients or that it influences treatment or other management choices. “Many biomarkers cannot achieve this,” he added.

Safety also has to be considered before rolling biomarkers into the clinic. If a prognostic biomarker, one that estimates the likelihood of recurrence, inaccurately predicts a patient’s cancer is likely to recur, it can cause harm by causing undue anxiety and unnecessary treatment. And if it inaccurately predicts a low risk of recurrence, it can cause harm by indicating treatment isn’t necessary when it might actually be beneficial.

The Food and Drug Administration (FDA) has to approve the safety and effectiveness of drugs before they can be used in the clinic. That approval is based on the results of well done clinical trials in large numbers of patients. But most biomarkers are laboratory-developed tests that require a different level of testing and FDA approval before becoming commercially available. Their widespread use instead is based mainly on the strength of limited clinical testing done on them, whether doctors adopt them, and whether medical society guidelines support their use.

The Use of Biomarker Testing

Dr. Polsky suggested that before doctors use a [biomarker test](#) on a particular patient, they consider whether the patient has similar traits to those on whom the biomarker was originally developed for. For example, a biomarker useful for melanomas originating in moles may not work for ones originating in the eye and vice versa, and a biomarker useful for advanced melanomas may not be valid for early stage tumors.

Dr. Polsky reported that the commercially available DecisionDX-Melanoma for patients is a test that uses genetic analysis of tumor tissue to classify patients with Stages I and II cutaneous melanomas as to whether they are low or high risk for disease recurrence. It is intended to help physicians decide the appropriate follow up for these patients. But in one study the test did not improve the prognostic accuracy beyond the degree of tumor thickness and ulceration already used to classify early-stage patients and determine follow up. In another study the test did not prove useful for Stage I patients and needed further testing to make conclusions about the usefulness in Stage 2 patients. Consequently, the National Comprehensive Cancer Network (NCCN) guidelines oncologists tend to follow did not recommend routine testing with DecisionDX-Melanoma outside of a clinical trial.

In contrast, the blood-based test for levels of lactate dehydrogenase (LDH), a molecule melanoma cells secrete, is such a good predictor of prognosis, it is used to determine substaging for melanoma patients. LDH is also being tested to see if it can help suggest optimal treatment strategies for melanoma patients.

A biomarker Dr. Polsky is particularly excited about and currently testing in his lab is circulating tumor DNA (ctDNA), which is released into the blood mainly from dead or dying tumor cells or inflammatory cells. Physicians currently use the test in lung cancer patients to determine the mutations in their tumors so they can adjust their therapy appropriately. Because it is a blood test, it avoids the need for a lung biopsy in these patients, Dr. Polsky noted. Physicians also use levels of ctDNA in the blood to monitor disease in some patients “because it is a lot easier than going for a CAT scan and you can do it more often,” he said. A study Dr. Polsky and his colleagues recently conducted in patients with melanoma suggests that levels of ctDNA could also be an early indicator of treatment effectiveness and potentially used to guide therapy.

Researchers are currently testing a number of other promising predictive or prognostic biomarkers for melanoma, including molecular markers on tumors and those that measure cells or compounds circulating in the blood. During his introduction to the session, Dr. Burkhard Jansen — Chief

Medical Affairs Officer at DermTech — stressed that “the use of biomarkers to guide clinical decision making has expanded dramatically and that this continues to be an exciting area of ongoing research.”

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