Best Practices for Effective Genomic Testing in Community Oncology

BY BRIDGET BARRY THIAS

The opportunity to offer precision medicine and clinical trials in community-based oncology practices brings procedures once only available in the academic research setting to community settings where most cancer patients are actually treated.

Despite the benefits of genomic testing, there are numerous barriers to comprehensive implementation in community cancer centers. The barriers include understanding when tests should be used, what tests should be used, how to interpret the results, and finding ways to make tests affordable within the health care system. Genomic germline testing is important to integrate beyond large university research medical centers.

iStock

Germline testing refers to the genetic workup of an individual while somatic testing or genetic evaluation of the tumor gives different information. Germline mutational analysis is important to properly identify individuals at risk for recurrence of certain cancers, as an example, *BRCA1*, *BRCA2*, and *ATM* mutations. The detection of deleterious mutations can help a patient understand the need for appropriate monitoring, prevention, or even treatment. Conversely, a negative test (absence of deleterious mutations) may eliminate the need for unnecessary additional screenings.

"Since community oncologists have the opportunity of seeing the majority of cancer patients or individuals at risk for cancer in the U.S., it is imperative that proper knowledge and operation on how to order such tests are present," said Lucio Gordan, MD, a board-certified oncologist/hematologist in Gainesville, Fla. "Oncologists may have to follow complex, manual processes that vary by insurer to determine patient coverage and reimbursement.

"Fortunately, there are industry leaders, like ION's Precision Medicine Advisory Panel, that are developing best practices and clinical programs to support implementation for more cancer centers," added Gordon, who is Vice President of Florida Cancer Specialists. The oncology group has approximately 100 locations in Florida and sees about 70,000 patients annually. Half of the patients have cancer and the other half have blood disorders.

Gordan said that in the past primarily only university medical research centers had the ability to analyze the genetic components of a tumor or a patient's blood, but now this same analysis can occur at community oncology centers.

Oncologists are looking for better guidance on when and how to offer patients genetic testing. They may receive inconsistent testing recommendations from various stakeholders, such as testing providers and drug manufacturers, and it can be hard to interpret best practices. ION Solutions/AmerisourceBergen called on its Precision Medicine Advisory Panel—comprised of oncologists, pharmacists, nurses, and administrative staff—to put together unbiased Precision Medicine Testing Recommendations.

"I am honored to be a part of this process, using my perspective and industry knowledge to better inform members of the considerations associated with tumor genomic and germline genetic testing and how best to identify patients who could most benefit from testing," Gordan said.

Understanding Clinical Advancements

Gordan noted it is important that oncologists are aware of the clinical advancements in genetic testing.

"Since community oncologists have the opportunity of seeing the majority of cancer patients or individuals at risk for cancer in the U.S., it is imperative that proper knowledge and operation on how to order such tests are present."

Understanding and properly testing patients and tissue are crucial to the proper selection of molecularly targeted drugs, inclusion in clinical trials, and potential utilization of immunotherapy. It is estimated that the majority of treatment decisions will involve knowledge and data on germline and somatic testing. There are numerous practical examples in the treatment of lung adenocarcinoma, colon, ovarian, and breast cancers among others. The development of new drugs is highly dependent on the information yielded from proper somatic genomic testing. It is critical that new drugs are designed for a precise patient population to enhance value, treatment success, and decrease toxicities. The cost of this testing can be a barrier to patient's ability to get the latest treatment.

"The economics of genetic testing can be a barrier for some patients right now. But, one of the goals of personalized medicine is to ultimately reduce costs by individualizing therapies. We want to pair the right person with the right treatment and risk assessment to yield a positive return on investment for the patient's health," Gordon explained. "For example, testing a patient for *BRCA* mutations prior to beginning standard, age-driven mammograms could determine if a patient needs to begin getting mammograms at a younger age to catch cancer earlier."

Oncologists can work with patients and their insurance companies to gather as much existing evidence as possible to make a sound argument for why genetic testing and treatment is necessary. For example, a report by Deloitte found that genetic testing for breast cancer patients saved about $1,900 per patient tested because it can reduce the use of chemotherapy by 20-35 percent (https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-au-economics-financial-impact-breast-cancer-180917.pdf).

Gordon shared the following recommendations:

- **Attend conferences and events for further information on implementing genomic testing:** "I regularly attend conferences and events that provide physicians, clinicians, and patient support staff with the opportunity to participate in educational sessions surrounding the clinical advancement of cancer treatment, including precision medicine and genomic testing. These opportunities allow oncologists to have their difficult and complex questions answered by colleagues and experts who are also implementing genomic testing into their practices."

Continued on page 29

Shorter Course of Radiation Therapy Effective in Prostate Cancer

A new UCLA-led study shows that men with low- or intermediate-risk prostate cancer can safely undergo higher doses of radiation over a significantly shorter period of time and still have the same successful outcomes as from a much longer course of treatment (*JAMA Netw Open* 2019;2(2):e188006).

This type of radiation, known as stereotactic body radiotherapy, is a form of external beam radiation therapy and reduces the duration of treatment from 45 days to 4-5 days. The approach has been in use since 2000 but has not yet been widely adopted because of concerns over how safe and effective this approach would be in the long term.

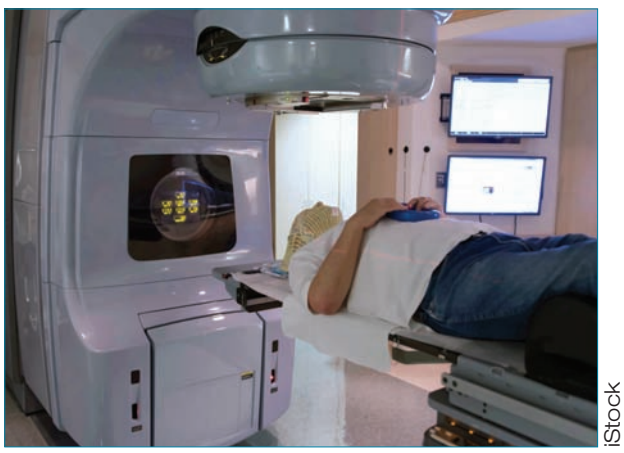
> "We've found that using stereotactic body radiotherapy, which has a higher dose of radiation, can safely and effectively be done in a much shorter time frame without additional toxicity."

"Most men with low- or intermediate-risk prostate cancer undergo conventional radiation, which requires them to come in daily for treatment and takes an average of 9 weeks to complete," said lead author Amar Kishan, MD, Assistant Professor of Radiation Oncology at the David Geffen School of Medicine at UCLA and researcher at the UCLA Jonsson Comprehensive Cancer Center.

"That can be very burdensome on a patient and be a huge interruption in their life. With the improvements being made to modern technology, we've found that using stereotactic body radiotherapy, which has a higher dose of radiation, can safely and effectively be done in a much shorter time frame without additional toxicity or compromising any chance of a cure."

Study Details

The UCLA research team analyzed data from 2,142 men with low- or intermediate-risk prostate cancer across multiple institutions who were treated with stereotactic body radiotherapy for prostate cancer between 2000 and 2012.



iStock

The men were followed for a median of 6.9 years. Just over half of the men had low-risk disease (53%), 32 percent had less aggressive intermediate-risk disease, and 12 percent had a more aggressive form of intermediate-risk disease.

The recurrence rate for men with low-risk disease was 4.5 percent, the recurrence rate for the less aggressive intermediate-risk was 8.6 percent, and the recurrence rate for the more aggressive intermediate-risk group was 14.9 percent. Overall, the recurrence rate for intermediate-risk disease was 10.2 percent. These are essentially identical to rates following more conventional forms of radiation, which are about 4-5 percent for low-risk disease and 10-15 percent for intermediate-risk disease.

"What is remarkable about this very large study is how favorably stereotactic body radiotherapy compares to all other forms of radiation treatments, both in terms of effectiveness and side effects," said senior author Christopher King, MD, PhD, Professor of Radiation Oncology and scientist at the UCLA cancer center. "With such long-term follow-up data, we can now offer this approach to patients with full confidence."

The research team at UCLA had previously found that stereotactic body radiation therapy was more cost-effective because of the fewer treatments involved. Other research has also suggested psychological benefits such as less regret about undergoing treatment. The current study now provides long-term data regarding the safety and clinical efficacy of this approach.

Kishan said the data show that the majority of the men followed are free of prostate cancer 7 years after treatment. He added that there was no evidence that this therapy caused worse toxicity in the long term.

"In fact," he noted, "we not only confirm that this method is both safe and effective, but we provide significant evidence that this could be a viable treatment option for men with low- and intermediate-risk of prostate cancer." OT

GENOMIC TESTING

continued from page 28

- **Leverage technology to gain access to recommendations on when and how to test patients, real-time industry updates, and educational resources:** "Physicians should continue to investigate and evaluate the available real-time, web-based portals that can provide them with precision medicine testing recommendations, as well as pertinent industry news, related clinical advancements, FDA approvals, and legislative updates. These portals allow oncologists to reference the resources they need quickly and efficiently, from any location and at any time. It puts the information physicians and their teams need at their fingertips."
- **Look for opportunities to share outcomes-based data to pave the way for testing:** "As more physicians use genomic testing, I anticipate an increase in outcomes-based data and that will need to be continually shared with payers and other stakeholders to further build support and resources for testing. Demonstrating the impact and patient implications of genomic testing can protect the longevity of precision medicine and allow physicians to connect cancer patients with some of the most effective treatment options." OT

Bridget Barry Thias is a contributing writer.

For More Information

- Art and Challenges of Precision Medicine: Interpreting and Integrating Genomic Data Into Clinical Practice (*Am Soc Clin Oncol Educ Book* 2018;(38):546-553)
- Implementing Precision Medicine Programs and Clinical Trials in the Community-Based Oncology Practice: Barriers and Best Practices (*Am Soc Clin Oncol Educ Book* 2018; doi:10.1200/EDBK_200633)