

Patients are willing to undergo multiple tests for new cancer treatments

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March 4, 2011 — Cancer patients are willing to undergo many tests to receive advanced experimental treatment in clinical trials, according to a new study by Mayo Clinic, Scottsdale Healthcare and the Translational Genomics Research Institute (TGen).

Researchers said patients' willingness to undergo tests bodes well for the future of personalized medicine, in which specific treatments are prescribed depending on the DNA genetic makeup of patients' tumors.

"This is the first study of its kind where [patients](#) themselves were asked what tests and medical imaging studies they would be willing to undergo while participating in clinical studies for their cancer. Patients also were asked how invasive they perceived such tests and studies," said Raoul Tibes, M.D. Ph.D., lead author of the study recently published online by the prestigious scientific journal *Cancer*, a physician-scientist for the Mayo Clinic in Arizona.

The study, Patient willingness to undergo pharmacodynamic and pharmacokinetic tests in early phase oncology trials, is scheduled for print publication in the July 15, 2011, edition of *Cancer*, published by the American Cancer Society.

To learn and understand more about the molecular aspects of cancer, researchers need tumor samples and images from tests like computed tomography (CAT) scans, magnetic resonance imaging (MRIs), positron emission tomography (PET) scans and other tests. Early-phase clinical

trials involve analyses of pharmacodynamics (what the drug does to the body) and pharmacokinetics (what the body does to a drug). The authors conducted a prospective study, examining patients' willingness to undergo such tests and the number of tests the patients would tolerate.

"What we learned is that patients are, in general, very willing to undergo additional, extra tests to participate in clinical studies," said Dr. Tibes, a former research doctor for TGen Clinical Research Service, a clinical-trials partnership of TGen and Scottsdale Healthcare at the Virginia G. Piper Cancer Center in Scottsdale.

"This study will provide valuable information, collected from actual patients, thereby informing clinical investigations in an era where we have more and more molecular-targeted therapies available, and our studies are more and more complex," Dr. Tibes said.

The study included 61 patients — 22 women and 39 men — with advanced malignancies.

The overall willingness to undergo study-required tests was very high, the study found. Patients were most willing to undergo urine, blood, ultrasound, x-rays, echocardiogram, PET and CAT scan studies. They were least willing to undergo tumor and skin biopsies and MRIs. However, most patients were at least willing to give one tumor biopsy sample per study, and often two.

"This is important information, because it tells us that we can design clinical studies that ask patients to give extra tumor biopsies. But we need to carefully judge of how many biopsies we request and what molecular tests we do with the tumor sample," said Mitesh J. Borad, M.D., Associate Director of Phase I Drug Development at the Mayo Clinic in Arizona and the study's senior author.

Inconvenience and prior negative experiences for more invasive tests, such as skin biopsies, modestly affected patients' willingness to undergo these tests again, the study found. Those patients with college educations and insurance coverage were more willing to undergo tests.

Dr. Tibes, who also is Associate Director of Mayo Clinic's Acute and Chronic Leukemia Program, said the study could serve as the basis of further exploration toward the design of patient-friendly, biomarker-driven clinical studies involving [cancer](#).

"We're taking those results forward," said Dr. Tibes, emphasizing the need for similar patient-oriented research, and to clearly communicate and educate patients about their treatment, including the goals of clinical research. "I think we need to hear it from the patients: 'This is what I'm willing to tolerate.' I think we need to ask patients more. It is crucially important."

Provided by The Translational Genomics Research Institute

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