MedicalXpress

Expensive, exploratory research biopsies overused in early studies of new cancer drugs

December 14 2015

For more than a decade, researchers studying the newest anticancer drugs have taken extra biopsies solely for the purpose of trying to understand the pharmacodynamics—what the drug does to the tumor—of a new anticancer drug. Such biopsies have been incorporated into studies sponsored by both the pharmaceutical industry and the National Cancer Institute. They are often mandatory in government-sponsored phase 1 clinical trials.

Now, a study by University of Chicago cancer specialists shows that this costly, sometimes risky, and often painful process has had no impact on subsequent drug development or how physicians use these new drugs to treat future patients.

The researchers identified 72 phase 1 studies of novel cancer drugs, published between 2003 and 2010, that involved such research biopsies. These studies included nearly 2,000 non-diagnostic biopsies of solid tumors. The tissue acquired from biopsies was used to study the biochemical and physiological effects of new drugs and the mechanism of their actions.

Only 12 of those studies, however, reported a significant biomarker result. Only five follow-up publications cited these studies and mentioned the biomarkers. None of the data collected was ever used to guide subsequent decisions about optimal drug doses.

These results, published Dec. 14, 2015, in the *Journal of Clinical*

Oncology "call into question the increasing use of such biomarkers in phase 1 studies," said study author Mark Ratain, MD, professor of medicine at the University of Chicago. "The process has had little or no impact on drug development or dose decisions."

The researchers focused on all studies published over the eight-year period that involved procurement of an invasive, non-diagnostic, post-treatment tumor biopsy. The 72 studies led to 1,873 biopsies. This figure, however, is likely low: 14 of the studies did not mention the number of biopsies performed. The researchers calculated the average cost of a biopsy for this purpose at about $6,675 per patient .

Only 12 of the 72 studies (17 percent) reported a statistically significant biomarker result. Only five later publications, reporting results from phase 2 or phase 3 trials of the same drugs, mentioned the previous biomarker studies.

No subsequent studies used the information from the biopsies to guide drug dose. They all recommended the maximum tolerated dose of those drugs, basing that decision on overall toxicity rather than the drugs' biologic activity as determined from biopsied tissue.

Many studies include these biopsies as a mandatory part of the protocol, so "patients have to consent to such studies if they want to receive the investigational drug, even though the biopsies in the studies we examined provided no research or clinical benefit," Ratain said.

Mandatory biopsies would be reasonable if they were of scientific value. But "our data shows that such studies have not had a scientific impact," Ratain said. "Institutional review boards should consider whether such exploratory tissue sampling is even ethical."

Ratain said that biopsy studies that are the primary endpoint are

ethical—if they are appropriately designed.

"Our findings argue that the use of invasive biopsies for the purpose of pharmacodynamics should be limited to clinical trials in which the primary objective is to ascertain the effect of the drug(s) on the biomarker," the authors conclude. "Given the risk and the cost, this issue requires further study."

Provided by University of Chicago Medical Center

Citation: Expensive, exploratory research biopsies overused in early studies of new cancer drugs (2015, December 14) retrieved 24 April 2024 from https://medicalxpress.com/news/2015-12-expensive-exploratory-biopsies-overused-early.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.