The value of randomized clinical trials in radiation oncology clinical practice

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This is Joel Tepper, M.D., senior author of the study. Dr. Tepper is Hector McLean Distinguished Professor of Cancer Research, professor of radiation oncology and a member of UNC Lineberger Comprehensive Cancer Center. Credit: UNC Lineberger Comprehensive Cancer Center

Cancer patients, physicians and insurers want to be sure that whatever therapy is recommended and provided to patients is based on evidence, preferably results from randomized clinical trials. But are there enough clinical trials data to provide this level of confidence?

A University of North Carolina School of Medicine study says not necessarily. Radiation oncologists evaluated how often patients were seen in their clinic with medical decisions to be made that were not specifically addressed by randomized controlled trials.

They determined that in a group of 393 patients who were being treated with curative intent with multiple tumor types, 47 percent of all medical decisions were made without available or applicable randomized evidence to inform clinical decision making.

The study is the only known published study to evaluate the availability of evidence in a routine clinical setting for any medical specialty. It was published in the June issue of the journal *Cancer*.

"Randomized controlled trials are the lynchpin of clinical care, but the results are often not applicable to an individual patient, so all care cannot be provided entirely on the basis of those trials. We're not speaking against clinical trials. We're just pointing out their limitations in daily cancer care," said Joel Tepper, MD, senior author. Dr. Tepper is Hector McLean Distinguished Professor of Cancer Research, professor of radiation oncology and a member of UNC Lineberger Comprehensive Cancer Center.

Dr. Tepper said the study draws attention to several issues. "The potential negative consequences of evidence-based coverage policies may impede necessary and appropriate patient care. If the standard of adequate evidence in the form of randomized clinical trials are often not generalizable to patients, the appropriateness of using randomized data

as the basis for coverage of every patient comes into question." Observational studies, trials conducted without randomization, are an option to inform decisions when randomized trials are not available.

"Additionally, we hope that our study results suggest that well-designed observational studies and alternative clinical trial designs may play a central role in the continued development of evidence for medical decision making in select patient groups," said Dr. Tepper. It also emphasizes the need for a robust clinical trial system that will generate more randomized trial data to inform clinical decision making.

"Our results also emphasize the importance of clinical judgment and experience in what we recommend to our patients. Tumor boards, when a patient's case is evaluated by a number of medical specialties, can also be extremely useful," he said.

The UNC group reviewed medical records of 393 patients evaluated for treatment in the UNC radiation oncology clinic. Patients with cancer of the breast (30 percent), head and neck (18 percent), and genitourinary (14 percent) were the most common tumor types included in the study. Patient medical decisions were classified as those with (Group 1) or without (Group 2) randomized clinical trials data. Group 1 was further divided into three groups based on the extent of fulfilling eligibility criteria for each randomized clinical trial: 1a) fulfilling all eligibility criteria; 1b) not fulfilling at least one minor eligibility criteria; and 1c) not fulfilling at least one major eligibility criteria. The availability of high level evidence varied by tumor type.

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