

Deviating from radiation protocols increases risk of treatment failure and death

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Implementing measures to ensure radiation therapy protocols are followed not only decreases deviations, but it can also improve overall survival in cancer patients, [Thomas Jefferson University Hospital](#) researchers suggest in a first-of-its kind study presented during a plenary session at the American Society for Radiation Oncology (ASTRO) 54th Annual Meeting in Boston.

Researchers from the [Department of Radiation Oncology at Jefferson](#) analyzed radiation therapy protocols, quality assurance (QA) measures and patient outcomes in eight, large clinical trials to determine if such deviations were associated with inferior clinical outcomes.

The findings, presented by Nitin Ohri, M.D., who conducted the research while at Jefferson, but is currently at Albert Einstein/Montefiore Medical Center in New York., revealed that deviating from protocols was associated with up to a 75 percent increased risk of [treatment failure](#) and overall mortality. This suggests that implementing QA measures to ensure protocols are followed could improve outcomes for cancer patients, according to the authors.

It is widely accepted that deviating from a radiation therapy protocol in a clinical trial will more than likely result in adverse effects. And, as a result, significant QA measures have been taken over the last several decades to minimize such effects. However, while these measures have shown to decrease deviation, there is currently no data establishing the patient-outcome benefits of those measures. This is the first study, to the

author's knowledge, to examine the effects on those measures on risk of treatment failures and mortality.

Examples of radiation therapy deviation include inadequate targeting of high-risk lymph node regions or incorrect dose calculation.

Other authors of the study include Adam P. Dicker, M.D., Ph.D., Chair of the Department of [Radiation Oncology](#) at Jefferson and the Kimmel Cancer Center at Jefferson, Laura Doyle, M.S., and Amy Harrison, M.S., of Jefferson's Department of Radiation Oncology, and Timothy Showalter, M.D., and Xinglei Shen, M.D.

The researchers examined two lung cancer trials, three trials for medulloblastoma, and trials for Ewing's sarcoma, pancreatic cancer and head and neck cancer, which included over 2,000 patients in total. They extracted information from the clinical trials, including number of patients included in QA analysis, definition of radiotherapy protocol deviation, and number of patients with and without radiotherapy deviations.

The frequency of radiation therapy deviations, they found, ranged from 8 percent to 71 percent. Those deviations were also associated with a significant decrease in overall survival, and with an approximately 75 percent increase in the risk of treatment failure and mortality.

"The magnitude of these effect sizes demonstrates that delivery of high-quality [radiation therapy](#) and having a rigorous QA program is critical for the successful execution of clinical trials and for the effective treatment of all cancer patients," said Dr. Dicker. "With such practices, deviations decrease and thus overall survival rates for cancer patients improve."

Provided by Thomas Jefferson University

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