



Stereotactic Lung Cancer Study Produces Positive Initial Results

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The initial phase of a clinical trial for treatment of early stage lung cancer has produced positive results, according to an article appearing Nov. 11 in the journal *Chest*.

Researchers at Indiana University School of Medicine reported that the results of the extracranial stereotactic radioablation Phase I study for non-small cell lung cancer led the group to continue with the second phase of the clinical trial.

The initial phase tested the toxicity of increasingly large doses of radiation precisely focused on the lung tumor. Enrollment in the trial began in February 2000 and 37 patients participated. Researchers report that surprisingly high doses of radiation were tolerated and 87 percent of patients had positive tumor response. Only six patients had local recurrence of cancer, all treated at the lower dose levels used at the onset of the trial. Local recurrence has not been observed to date at the highest levels.

Patients enrolled in the Phase I study had to have stage I non-small cell lung cancer that was medically inoperable because of extenuating health problems. Non-small cell lung cancer accounts for 80 percent of all lung cancers and is the leading cause of cancer-related fatalities in the United States. In the U.S., 170,000 new cases of lung cancer are diagnosed each year and there are 157,000 deaths caused by the disease.

"Lung cancer patients frequently have other health problems such as emphysema or heart disease that makes them a bad risk for the standard surgical therapy for their disease," said Robert Timmerman, M.D., associate professor of radiation oncology and the principal author of the article.

Using a painless, minimally invasive therapy, Timmerman and his IU colleagues used 3-D imaging and stereotactic body mapping to precisely target the tumor down to a millimeter so that healthy tissue was spared the intensity of the photon radiation. Stereotactic mapping utilizes a specially designed, lightweight body frame that limits mobility to ensure the precision of photon beams aimed at the tumor.

"The results of the first phase were very encouraging and somewhat surprising," Dr. Timmerman said. "We thought patients would only tolerate lower doses of radiation since they were frail to begin with. To our delight, we were able to

increase dose levels without prohibitive toxicity. In the end, the therapy should be extremely potent against that cancer."

Early stage lung cancer traditionally is treated with surgery, conventional radiation, or both. There is a 60 percent to 70 percent cure rate for early stage lung cancer in patients undergoing surgery and a 20 percent to 30 percent cure rate for those treated with conventional radiation, which involves five weeks to six weeks of daily radiation treatments.

The stereotactic treatment plan involved only three outpatient treatments but at a much higher dose rate than conventional radiation.

The Phase I study was completed in December 2001. Phase II of the study began in January 2002 and 48 patients have been enrolled. This second phase seeks to quantify beneficial aspects of the therapy such as survival and local disease control when radiation is delivered at the highest dose levels. Individuals interested in enrolling in the study or those wanting additional information may contact Tia Whitford, R.N., at 317-278-7267.

"This study holds promise for a group of patients who had few good options," says Dr. Timmerman. "It is hoped the stereotactic treatments not only will give medically frail patients with early stage lung cancer a choice but perhaps someday be another option for a larger spectrum of lung cancer patients."