進行肺がんに対して低線量放射線療法は高線量よりも優れている（Abstract＃7501）

Stage III非小細胞肺がん患者に対する標準線量の放射線療法は高線量よりもより安全で有効である

Standard-dose radiation is safer and more effective than high-dose for patients with stage III non-small cell lung cancer

第49回ASCO年次集会で発表された第III相試験の結果、stage III非小細胞肺がん患者に対する標準線量（SD:60 Gy）の放射線療法は高線量（HD:74 Gy）よりも治療の有効性および生存期間両者の観点から優れていることが示された。研究者らは464人の患者を標準的な化学療法（パクリタキセルとカルボプラチン）にSDまたはHDによる放射線治療を併用する群に無作為に割り付けた。生存期間中央値はSD放射線療法を施行された患者においてHD放射線療法群患者よりもはるかに長く（28.7か月対19.5か月）、推定18か月全生存率もたSD群で高かった（66.9%対53.9%）。18か月時点でのがん再発率はHD群においてSDと比較し高かった（局所再発率34.3%対25.1%、遠隔再発率44%対35.3%）。ほとんどの患者の主要死因は肺がんであったが、治療関連死数はHD群（10）でSD群（2）よりも著明に多かった。この患者集団におけるHD治療は第I相や第II相臨床試験では有望に思えたが、今回のスタディではそうではないことを明確に示している。

Full Text

A phase III trial in patients with stage III non-small cell lung cancer (NSCLC) concludes that standard dose (SD) radiotherapy (60 Gy) is safer and more effective than high-dose (HD) radiotherapy (74 Gy), extending survival by nine months and causing fewer treatment related deaths. While 60 Gy is already standard, many doctors use higher doses expecting better outcomes. These findings should put an end to higher-dose treatment, given better outcomes in the standard dose arm.

Although HD therapy in this patient population appeared promising in earlier phase I and phase II clinical trials, this study clearly shows that it is associated with dramatically shorter survival.

"We expected at the outset that high-dose radiation therapy would lead to better outcomes. We were surprised, though also pleased, to discover that less intense treatment led to better control of cancer progression and spread, and even improved overall survival," said lead author Jeffrey D. Bradley, M.D., a professor of radiation oncology at the Washington University School of Medicine in St. Louis, Missouri, USA. "The biological reasons for failure of the high dose with respect to overall survival and local-regional control are not readily apparent."

In the study, 464 patients were randomly assigned to treatment with SD or HD radiation therapy along with standard chemotherapy (paclitaxel and carboplatin). In each treatment arm, the patients were also randomly assigned to receive cetuximab or no additional therapy. Data on the effects of cetuximab on survival will be reported at a later date. The HD arm was closed after an interim analysis showed it was not superior to the SD arm.

The median survival for patients who received SD radiation therapy was much longer compared to that in patients who received HD radiation therapy (28.7 months vs. 19.5 months) and the estimated 18-month overall survival rates were also higher for the SD arm (66.9 percent vs. 53.9 percent). Cancer recurrence rates at 18 months were higher in the HD group of patients compared with the SD group (local recurrence rates were 34.3 percent vs. 25.1 percent, and distant recurrence rates were 44 percent vs. 35.3 percent). While the primary cause of death for most patients was lung cancer, there were a notably higher number of treatment-related deaths in the HD arm (10), compared to the SD arm (2).

"This is a critical study in the field of radiation oncology. After a decade of research, we can finally close the chapter on high-dose vs. standard-dose therapy debate in lung cancer therapy, using evidence-based data to improve care for our patients," said ASCO President Sandra M. Swain, M.D., FACP.

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