

Patient-reported outcomes provide valuable insight regarding quality of life for patients with NSCLC

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An analysis of quality of life (QOL) data of stage III lung cancer patients who received higher doses of radiation therapy (with chemotherapy) shows a significantly lower quality of life at 3 months after treatment compared to patients who received a standard dose of radiation (with chemotherapy), according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 55th Annual Meeting. The study also suggests that lung cancer patients who received intensity modulated radiation therapy (IMRT) reported less decline in their QOL compared to those receiving three-dimensional conformal radiation therapy (3-D CRT).

Patient data was compiled from the RTOG 0617 study, a phase III, [randomized clinical trial](#) of patients with locally advanced non-small cell lung cancer (NSCLC) conducted from 2007 to 2011. The randomized study compared a high-dose (HD) of 74 Gy to a standard dose (SD) of 60 Gy. All enrolled patients received concurrent chemotherapy of carboplatin/paclitaxel, and they were also randomized to be treated with or without [cetuximab](#) (C225). The radiation was administered with two types of [radiation therapy](#) (RT): 3-D CRT, in which beams of radiation are shaped to match the tumor, or IMRT, a more sophisticated technique that uses a computer-controlled algorithm to modify the intensity of each beam to further spare normal tissue. While the study was not randomized for the radiation treatment technique (3-D CRT or IMRT), the pretreatment characteristics were not significantly different for these

techniques except that higher stage tumors were treated with IMRT. Prior results of a planned analysis of the trial determined that the higher dose of radiation therapy was associated with lower overall survival (OS), and, at that point, the high-dose radiation therapy arms of the study were closed.

Because the RTOG study indicated that OS rates were lower with higher doses of radiation, despite few differences in provider-reported toxicity between the study's arms, researchers evaluated if patient-reported outcomes had any bearing on the results of the RTOG 0617 trial. Patient QOL scores were compared between the treatment arms, as well as between the RT techniques. QOL information was collected using the Functional Assessment of Cancer Therapy-Trial Outcome Index (FACT-TOI), which is a compilation of physical well being (PWB), functional well being (FWB), and lung cancer subscale (LCS) results. Results were studied at baseline, at the end of chemoradiation, and at three months and 12 months post-treatment. Two-sample t-tests, the Wilcoxon-Mann-Whitney test and the Chi-Square test compared QOL between arms and between technologies (3-D CRT vs. IMRT) via two-sided p values and effect sizes (ES).

Baseline FACT-TOI were completed from each arm on 88 percent of patients, with no difference in patient demographics, baseline QOL scores or C225 use. Seventy-one percent of patients completed QOL data at three months, of whom approximately 60 percent of patients (225) completed it at 12 months.

The primary QOL hypothesis was that there would be a significant difference between arms at 3 months using the LCS, which focuses on key symptoms of lung cancer. A clinically meaningful decline (CMD) in LCS for patients receiving 74 Gy was significantly higher at three months post-treatment (46 percent) than for patients receiving 60 Gy (31 percent, $p=0.024$, ES 0.4); yet these differences resolved by 12 months,

with the 74 Gy dose producing a CMD of 36 percent, and the 60 Gy dose producing a CMD of 39 percent ($p=0.7$, ES

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